EXHIBIT 69 SUBMITTED UNDER SEAL

		Page 1
1	CONFIDENTIAL	Volume I Pages 1 to 222
2 3		Exhibits 1 - 18
4	UNITED STATES DISTF DISTRICT OF MASSA	
5 6		x
		:
7	BRIANNA BOE, et al.,	:
	Plaintiffs,	:
8	UNITED STATES OF AMERICA,	:
9	Intervenor Plaintiff,	: Civil Action No.
2	vs.	: 2:22-cv-184-LCB
10		:
	HON. STEVE MARSHALL, in his	:
11	official capacity as Attorney	:
	General of the State of	:
12	Alabama, et al.	:
	Defendants.	:
13		:
14		X
14 15		
тJ	CONFIDENTIAL DEPOSITIC	N OF JENIFER
16	LIGHTDALE, M.D., a witness call Defendants, taken pursuant to t	led on behalf of the
17	Civil Procedure before Carol H.	
	Professional Reporter and Notar	_
18	the Commonwealth of Massachuset Holland & Knight, LLP, 10 St. J	tts, at the Offices of
19	Massachusetts, on Monday, May 6 9:12 a.m.	
20		
21		
22		
	APPEARANCES ON PAGE 2	
23		
24		

1 .	Page 2		EVIII DITS (Centinged)	Page 4
	PRESENT:	1	E X H I B I T S (Continued) NO. DESCRIPTION PAGE	
2			Exhibit 5 Pages S1-S4 and S247-S258 from 54	
2	GLBTQ Legal Advocates and Defenders		article entitled "Standards of	
3	(by Jennifer Levi, Esq.)	4	Care for the Health of	
	18 Tremont Street, Boston, MA 02108,		Transgender and Gender Diverse	
4	617.388.5140, jlevi@glad.org - and -	5	People, Version 8," by E.	
5	Human Rights Campaign (Via Zoom)	6	Coleman, et al., from	
5	(by Cynthia Cheng-Wun Weaver, Esq.)	6	International Journal of Transgender Health, 2022	
	1640 Rhode Island Avenue, NW,	7	Hansgehuer Hearth, 2022	
6	Washington, DC 20009, 202.527.3669, Cvnthia.Weaver@hrc.org - and -		Exhibit 6 Article entitled "GRADE 67	
7		8	guidelines: 3. Rating the	
7	King & Spalding LLP (Via Zoom)		quality of evidence," by Howard	
8	(by Katherine Vessels, Esq.)	9	Balshem, et al., from Journal	
0	1700 Pennsylvania Avenue, NW, Washington,	10	of Clinical Epidemiology, 2011	
0	DC 20005, 202.737.0500, kvessels@kslaw.com,	10	Exhibit 7 Article entitled "Guidelines 87	
9	for the Plaintiffs.	11	for sedation and anesthesia in	
10	United States Department of Justice (Via Zoom)		GI endoscopy," by Dayna S.	
11	(by James Fletcher, Esq.)	12	Early, M.D., et al., from	
11	150 M Street, NE, Washington, DC		Gastrointestinal Endoscopy,	
	20530, James.Fletcher@usdoj.gov,	13	2018	
12	202.598.0083, for the Intervenor	14	Exhibit 8 Article entitled "GRADE 93	
	Plaintiff.		guidelines: 14. Going from	
13		15	evidence to recommendations:	
	Alliance Defending Freedom	16	the significance and presentation of	
14	(by Roger G. Brooks, Esq.)	10	recommendations," by Jeff	
	15100 N. 90th Street, Scottsdale, AZ 85260,	17	Andrews, et al., from Journal	
15	480.444.0200, rbrooks@adflegal.org,		of Clinical Epidemiology, 2013	
	for the Defendants.	18		
16		1	Exhibit 9 Article entitled "GRADE 101	
17	Also Present: Shannon Minter, Esq. (Via Zoom)	19	guidelines: 15. Going from	
18			evidence to recommendation	
19	* * * *	20	determinants of a	
20		21	recommendation's direction and strength," by Jeffrey C.	
21		21	Andrews, et al., from Journal	
22		22	of Clinical Epidemiology, 2013	
23		23	1 657	
24		24		
	D 2			D 5
1	Page 3			
		1	E X H I B I T S (Continued)	rage .
2	INDEX	1 2	E X H I B I T S (Continued) NO. DESCRIPTION PAGE	rage .
		2		rage .
	INDEX	2 3	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac-	r age .
2	INDEX	2	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled	rage .
2 3	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS	2 3 4	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan	r age .
2 3	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE,	2 3	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming	r age .
2 3 4	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7	2 3 4	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the	r age J
2 3 4 5 6	I N D E X WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D.	2 3 4 5	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming	r age .
2 3 4 5 6 7	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 ****	2 3 4 5	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages	r age .
2 3 4 5 6 7 8	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** EXHIBITS	2 3 4 5 6 7	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109	r age .
2 3 4 5 6 7 8 9	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE	2 3 4 5 6	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and	r age .
2 3 4 5 6 7 8 9	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10	2 3 4 5 6 7 8	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8." Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender	r age .
2 3 4 5 6 7 8 9 10	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement	2 3 4 5 6 7	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entilled 103 "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 109 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a 109	r age .
2 3 4 5 6 7 8 9	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and	2 3 4 5 6 7 8 9	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline	r age .
2 3 4 5 6 7 8 9 10 11	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric	2 3 4 5 6 7 8	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entilled 103 "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 109 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a 109	r age .
2 3 4 5 6 7 8 9 10	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint	2 3 4 5 6 7 8 9	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo	r age .
2 3 4 5 6 7 8 9 10 11 12	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by	2 3 4 5 6 7 8 9 10 11	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entilled 103 "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 109 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 109 Exhibit 12 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo 109	r age .
2 3 4 5 6 7 8 9 10 11	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al.,	2 3 4 5 6 7 8 9 10 11 12	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled 103 "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 109 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 101 Exhibit 12 Article entitled "Patient IS 111	r age .
2 3 4 5 6 7 8 9 10 11 12 13	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric	2 3 4 5 6 7 8 9 10 11	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled 103 "Draft 12-point Strategic Plan to Advance Gender Affirming 104 Care through strengthening the WPATH SOC-8." Bates Pages 109 BOEAL_WPATH_091211-91218 109 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient sedation using capnography	r age .
2 3 4 5 6 7 8 9 10 11 12	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al.,	2 3 4 5 6 7 8 9 10 11 12 13	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled 103 "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 109 Exhibit 11 Article entitled "Clinical adolescents experiencing gender 109 dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo 109 Taylor, et al., from Archives of Disease in Childhood, 2024 111 Exhibit 12 Article entitled "Patient sedation using capnography monitoring: a systematic review	r age .
2 3 4 5 6 7 8 9 10 11 12 13	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition,	2 3 4 5 6 7 8 9 10 11 12	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled 103 Toraft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri	r age .
2 3 4 5 6 7 8 9 10 11 12 13 14	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition,	2 3 4 5 6 7 8 9 10 11 12 13 14	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled 103 "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 109 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 111 Exhibit 12 Article entitled "Patient sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British 111	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022	2 3 4 5 6 7 8 9 10 11 12 13 14 15	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric 10 Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13	2 3 4 5 6 7 8 9 10 11 12 13 14 15	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled 103 "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 109 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 111 Exhibit 12 Article entitled "Patient sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British 111	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research &	2 3 4 5 6 7 8 9 10 11 12 13 14 15	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient adometa-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric 10 Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December 2017	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 111 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 119 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 119	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** EXHIBITS NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December 2017 Exhibit 3 Ten-page printout from WPATH 37	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8." Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 Exhibit 14 Article entitled "Effects of 126	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December 2017 Exhibit 3 Ten-page printout from WPATH 37 website entitled "methodology	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 Exhibit 14 Article entitled "Effects of Intravenous Secretin on	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** E X H I B I T S NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December 2017 Exhibit 3 Ten-page printout from WPATH 37 website entitled "methodology	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 119 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 126 Exhibit 14 Article entitled "Effects of Language and Behavior of 126	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** EXHIBITS NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December 2017 Exhibit 3 Ten-page printout from WPATH 37 website entitled "methodology for the development of soc8"	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 111 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 119 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 126 Exhibit 14 Article entitled "Effects of Lintravenous Secretin on Language and Behavior of Children With Autism and 126	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** EXHIBITS NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December 2017 Exhibit 3 Ten-page printout from WPATH 37 website entitled "methodology for the development of soc8" Exhibit 4 Expert Rebuttal Declaration of 51	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 Exhibit 14 Article entitled "Effects of Language and Behavior of Children With Autism and Gastrointestinal Symptoms: A	Γ age .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** EXHIBITS NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December 2017 Exhibit 3 Ten-page printout from WPATH 37 website entitled "methodology for the development of soc8" Exhibit 4 Expert Rebuttal Declaration of 51 Jenifer R. Lightdale, M.D.,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entitled "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entitled "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo Taylor, et al., from Archives of Disease in Childhood, 2024 111 Exhibit 12 Article entitled "Patient 111 safety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 119 Exhibit 13 Article entitled "Assessing the 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 126 Exhibit 14 Article entitled "Effects of Lintravenous Secretin on Language and Behavior of Children With Autism and 126	Fage .
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	INDEX WITNESS DIRECT CROSS REDIRECT RECROSS JENIFER LIGHTDALE, M.D. BY MR. BROOKS 7 **** EXHIBITS NO. DESCRIPTION PAGE Exhibit 1 Article entitled "Pediatric 10 Endoscopy Quality Improvement Network Quality Standards and Indicators for Pediatric Endoscopic Procedures: A Joint NASPGHAN/ESPGHAN Guideline," by Jenifer R. Lightdale, et al., from Journal of Pediatric Gastroenterology and Nutrition, March 2022 Exhibit 2 Document entitled "Appraisal of 13 Guidelines for Research & Evaluation II, AGREE II Instrument," updated December 2017 Exhibit 3 Ten-page printout from WPATH 37 website entitled "methodology for the development of soc8" Exhibit 4 Expert Rebuttal Declaration of 51 Jenifer R. Lightdale, M.D.,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	NO. DESCRIPTION PAGE Exhibit 10 Two-page chain of emails dated 103 February 7, 2023, with redac- tions, with attachment entilted "Draft 12-point Strategic Plan to Advance Gender Affirming Care through strengthening the WPATH SOC-8," Bates Pages BOEAL_WPATH_091211-91218 Exhibit 11 Article entilted "Clinical 109 guidelines for children and adolescents experiencing gender dysphoria or incongruence: a systematic review of guideline quality (part 1)," by Jo 109 Taylor, et al., from Archives of Disease in Childhood, 2024 111 Satety during procedural sedation using capnography monitoring: a systematic review and meta-analysis," by Rhodri Saunders, et al., from British Medical Journal Open, 2017 111 Exhibit 13 Article entilted "Satessing the 119 119 Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Alejandro R. Jadad, M.D., et al., from Controlled Clinical Trials, 1996 126 Exhibit 14 Article entilted "Effects of Language and Behavior of Children With Autism and Gastrointestinal Symptoms: A Single-Blinded, Open-Label 126	Page 5

	CONTIL		
1	Page 6 E X H I B I T S (Continued)	1	Page 8
2	NO. DESCRIPTION PAGE	1	A. Correct.
3	Exhibit 15 Excerpts from Institute of 141 Medicine book entitled Clinical	2	Q. You're not an expert in neurology or
4	Practice Guideline We Can	3	cognition?
5	Trust, Robin Graham, et al., Editors	4	A. No.
	Exhibit 16 Article entitled "Evaluating 187	5	Q. Do you have any publications relating to
7	Patient-Centered Outcomes in Clinical Trials of Procedural	6	mental health at all?
8	Sedation, Part 2, Safety: Sedation Consortium on	7	A. Yes. I think somewhere back there there's
0	Endpoints and Procedures for	8	something about kids with IBD and going to college.
9	Treatment, Education, and Research Recommendations," by	9	That's, like, maybe ten years ago. I worked with a
10	Denham S. Ward, M.D., et al.,	10	fellow.
11	from Anesthesia & Analgesia, 2018	11	Q. Do you have any expertise at all relating
	Exhibit 17 Article entitled "Risk Factors, 199	12	to gender dysphoria or gender identity?
13	Morbidity, and Treatment of Thrombosis in Children and	13	A. No.
14	Young Adults With Active Inflammatory Bowel Disease," by	14	Q. Have you ever diagnosed any patient with
14	Naamah L. Zitomersky, et al.,	15	gender dysphoria?
15	from Journal of Pediatric Gastroenterology and Nutrition,	16	A. No.
16	September 2013	17	Q. Have you ever treated a patient for
	Exhibit 18 Article entitled "The Dutch 214 Protocol for Juvenile	18	anything who, to your knowledge, suffered from
18	Transsexuals: Origins and	19	gender dysphoria?
19	Evidence," by Michael Biggs, from Journal of Sex & Marital	20	A. Yes.
20	Therapy, 2022	21	Q. But your treatment had nothing to do with
	* * * *	22	the gender dysphoria?
21 22		23	A. Correct.
23 24		24	Q. All right. Do you consider yourself to be
-	Dece 7		
1	Page 7 P R O C E E D I N G S	1	Page 9 an expert in medical ethics?
$\begin{vmatrix} 1\\2 \end{vmatrix}$	JENIFER LIGHTDALE, M.D.	$\begin{vmatrix} 1\\2 \end{vmatrix}$	A. No.
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	a witness called for examination by counsel for the	3	Q. You've never taught a course in medical
4	Defendants, having been satisfactorily identified by	4	ethics?
5	the production of her driver's license and being	5	A. No.
6	first duly sworn by the Notary Public, was examined	6	Q. And other than a basic medical school
7	and testified as follows:	7	course, have you had any special training in medical
8	DIRECT EXAMINATION	8	ethics?
9	BY MR. BROOKS:	9	A. Yes. As part of conducting research, you
10	Q. Dr. Lightdale, good morning.	10	have to get trained in responsible conduct of
11	Let me start by making sure that I	10	research. So I have done that.
11	understand the scope of the expertise that you're	12	Q. You did not have any role at all in the
12	bringing to the table.	12	development of the WPATH Standards of Care Version
13	You're not a psychiatrist, correct?	13	8, did you?
14	A. I am not a psychiatrist.	14	A. No.
15	Q. Nor a psychologist?	15	Q. Nor any version of the WPATH Standards of
17	A. No.	10	Q. Not any version of the wPATH Standards of Care?
17	Q. You don't have any degree relating to	17	A. No.
18		18	
20	psychology? A. No.	19 20	Q. And you weren't, at any stage, invited to review or comment on a draft?
20		-	
	Q. You're not an expert in adolescent	21	A. No.
22	developmental psychology?	22	Q. Do you have any knowledge of who comprises

A. No.

Q. Or indeed adolescent anything, correct?

23

24

24

23 the membership of WPATH?

A. No.

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 5 of 58

CONFIDENTIAL

	D 10		D 12
1	Page 10 Q. Do you have any knowledge of the process	1	Page 12 follow the AGREE II methodology to actually develop
$\begin{vmatrix} 1\\2 \end{vmatrix}$	that was used to develop the WPATH SOC-8 other than	$\begin{vmatrix} 1\\2 \end{vmatrix}$	our guidelines."
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	the methodology web page you refer to in your expert	3	Q. So let me break that into two halves. I
4	report?	4	think what you first said is that AGREE II, what its
5	A. No. Just the web page.	5	primary function is is a methodology to evaluate
6	Q. And you're not a member of the Endocrine	6	maybe "quality" is not the right word, but the
7	Society, correct?	7	quality of a set of clinical practice guidelines; is
8	A. No.	8	that right?
9	A. No.Q. And do you have any knowledge at all as to	9	A. Yeah. I wouldn't say "quality" is the
10	the policies or procedures followed by any gender	10	right word. It is a way to look at how guidelines
10	clinic in Alabama?	11	are developed and to really say that they met
12	A. No.	12	certain steps. And, you know, you can think of it
12	MR. BROOKS: Let me ask the reporter to	12	as a strategy, you can think of it as a framework,
13	mark as Exhibit 1 an article from 2022 with such a	14	and it's a way of assessing the guidelines.
15	long title, "Pediatric Endoscopy Quality Improvement	15	Q. Assessing them with for what purpose?
16	Network Quality Standards," and it goes on from	16	That is, are you trying to find out their
17	there, of which Dr. Lightdale is the first author.	17	reliability? You said "quality" isn't the right
18	(Document marked as Lightdale	18	word, but assessment towards what end?
19	Exhibit 1 for identification)	19	A. So basically it is, in the end they want to
20	Q. Dr. Lightdale, is this in fact a paper of	20	appraise the guidelines and to say did they meet
21	which you are the lead author?	21	certain points of developing it.
22	A. Yes.	22	You know yeah.
23	Q. And can you generally describe for the	23	Q. But the purpose isn't simply to award a
	record what this paper is.	24	gold star. The purpose is to give clinicians some
	* *		
	Page 11		Page 12
1	Page 11 A Yes So this is one of five documents that	1	Page 13 comfort that these guidelines are reliable: am I
1	A. Yes. So this is one of five documents that	1	comfort that these guidelines are reliable; am I
2	A. Yes. So this is one of five documents that came out of a joint process of a society that I	2	comfort that these guidelines are reliable; am I correct?
2 3	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the	23	comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a
2 3 4	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology	2	comfort that these guidelines are reliable; am I correct?A. You know, you can use AGREE II and make a decision that you're not going to follow certain
2 3 4 5	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European	2 3 4	comfort that these guidelines are reliable; am I correct?A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what
2 3 4	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology	2 3 4 5 6	comfort that these guidelines are reliable; am I correct?A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into
2 3 4 5 6	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were	2 3 4 5 6	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a
2 3 4 5 6 7	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology	2 3 4 5 6 7	comfort that these guidelines are reliable; am I correct?A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into
2 3 4 5 6 7 8	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to	2 3 4 5 6 7 8	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but
2 3 4 5 6 7 8 9	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to	2 3 4 5 6 7 8 9	comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C.
2 3 4 5 6 7 8 9 10	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy.	2 3 4 5 6 7 8 9 10	comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was,
2 3 4 5 6 7 8 9 10 11	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the	2 3 4 5 6 7 8 9 10 11	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of
2 3 4 5 6 7 8 9 10 11 12	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into	2 3 4 5 6 7 8 9 10 11 12	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set
2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the	2 3 4 5 6 7 8 9 10 11 12 13	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct?
2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of	2 3 4 5 6 7 8 9 10 11 12 13 14	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct? A. Yeah. We work as a group again, I'm
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of Guidelines for Research and Evaluation," and it	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct? A. Yeah. We work as a group again, I'm working with Europeans here and a lot of North Americans, so it's a huge group of people. And I think for keeping us all on the same page, AGREE II
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of Guidelines for Research and Evaluation," and it refers to AGREE II. Can you explain what AGREE II is. A. Yes. So AGREE II, in my words, when I talk 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct? A. Yeah. We work as a group again, I'm working with Europeans here and a lot of North Americans, so it's a huge group of people. And I think for keeping us all on the same page, AGREE II gave us a framework to work in.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of Guidelines for Research and Evaluation," and it refers to AGREE II. Can you explain what AGREE II is. A. Yes. So AGREE II, in my words, when I talk about it, is a framework or it's basically a way	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct? A. Yeah. We work as a group again, I'm working with Europeans here and a lot of North Americans, so it's a huge group of people. And I think for keeping us all on the same page, AGREE II gave us a framework to work in. Q. All right.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of Guidelines for Research and Evaluation," and it refers to AGREE II. Can you explain what AGREE II is. A. Yes. So AGREE II, in my words, when I talk about it, is a framework or it's basically a way that you can decide that a guideline has been	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct? A. Yeah. We work as a group again, I'm working with Europeans here and a lot of North Americans, so it's a huge group of people. And I think for keeping us all on the same page, AGREE II gave us a framework to work in. Q. All right. MR. BROOKS: I'm going to ask the reporter
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of Guidelines for Research and Evaluation," and it refers to AGREE II. Can you explain what AGREE II is. A. Yes. So AGREE II, in my words, when I talk about it, is a framework or it's basically a way that you can decide that a guideline has been developed in a methodologically sound way. And so	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct? A. Yeah. We work as a group again, I'm working with Europeans here and a lot of North Americans, so it's a huge group of people. And I think for keeping us all on the same page, AGREE II gave us a framework to work in. Q. All right. MR. BROOKS: I'm going to ask the reporter to mark as Exhibit 2 a document entitled "AGREE II
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of Guidelines for Research and Evaluation," and it refers to AGREE II. Can you explain what AGREE II is. A. Yes. So AGREE II, in my words, when I talk about it, is a framework or it's basically a way that you can decide that a guideline has been developed in a methodologically sound way. And so it's basically something you use, frankly, usually	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct? A. Yeah. We work as a group again, I'm working with Europeans here and a lot of North Americans, so it's a huge group of people. And I think for keeping us all on the same page, AGREE II gave us a framework to work in. Q. All right. MR. BROOKS: I'm going to ask the reporter to mark as Exhibit 2 a document entitled "AGREE II Instrument" dated December 2017.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. So this is one of five documents that came out of a joint process of a society that I actually currently am the president of, which is the North American Society of Pediatric GI, Hepatology and Nutrition, or NASPGHAN, with the European Society of Pediatric Gastroenterology, Hepatology and Nutrition, which is ESPGHAN. And what we were doing for quite some time was working together to come up with joint standards and also ways to measure high-quality pediatric endoscopy. Q. Now, in the abstract, in Column 1 of the first page of Exhibit 1, about two inches down into the abstract, it states that this project "used the methodological strategy of the Appraisal of Guidelines for Research and Evaluation," and it refers to AGREE II. Can you explain what AGREE II is. A. Yes. So AGREE II, in my words, when I talk about it, is a framework or it's basically a way that you can decide that a guideline has been developed in a methodologically sound way. And so it's basically something you use, frankly, usually after the fact. But in our case, we said, "Let's	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 comfort that these guidelines are reliable; am I correct? A. You know, you can use AGREE II and make a decision that you're not going to follow certain steps. So it's really just a way of laying out what are all the different things that can go into building a guideline, and then you can look at a guideline and say, Yup, they met X, Y and Z, but they decided not to do A, B and C. Q. Okay. And I think then what you said was, for your project, you decided to create a set of guidelines with an eye already on the criteria set forth by AGREE II, correct? A. Yeah. We work as a group again, I'm working with Europeans here and a lot of North Americans, so it's a huge group of people. And I think for keeping us all on the same page, AGREE II gave us a framework to work in. Q. All right. MR. BROOKS: I'm going to ask the reporter to mark as Exhibit 2 a document entitled "AGREE II

4 (Pages 10 - 13)

Page 14 1 Q. And let me ask you first to take a look at 1 concept of you do it in a good way, yes	
1 Q. And let me ask you first to take a look at 1 concept of you do it in a good way, yes	Page 16
2 this and identify it for the record, if you can. 2 Q. And we'll talk more about what t	
3 A. Sure. This looks like a pdf of the AGREE 3 A. Okay.	that means.
4 II, what they call the Instrument. 4 U, what they call the Instrument. 4 U, what they call the Instrument.	sentence
5 Q. And explain to me what the Instrument 5 says, "The quality of guidelines can be	
6 what the AGREE Instrument is. 6 variable and some often fall short of bas	-
7A. So I can't say I'm completely familiar with7standards."	
8 this exact, you know, document, but an instrument is 8 Do you see that language?	
9 essentially a tool you can use to apply something. 9 A. Yes.	
10 So I presume it's something to apply to AGREE II. 10 Q. And is that consistent with your	own
11 Q. And it says that it's put out by The AGREE 11 observation in your professional life?	0.001
12 Next Steps Consortium. Is that a group or a name 12 A. Yes.	
13 that means anything to you? 13 Q. That is, you have seen many doc	cuments that
14 A. Not exactly. So I think AGREE is something 14 claim to be clinical practice guidelines	
15 I was aware of. And then what was more important 15 short of basic standards?	
16 for me is it was updated, and it's been updated 16 A. No, I wouldn't say that. I would	say I've
17 now that's why it's now AGREE II and this 17 been in the field of medicine longer tha	-
18 update was actually 2017. 18 have been around. And so you've watch	-
19 And why that's relevant is this thing that 19 evolution in how guidelines come abou	
20 we talked about before was actually started in, 20 actually are ready to consider a clinical	
21 like, 2018. So everybody was talking about AGREE II 21 guideline, if you will.	-
22 as, you know, a way that used a framework. 22 And this again, there's been a lo	ot of
23 Q. Okay. Let me ask you to turn in this 23 evolution around this, but there's an effe	fort to try
24 document and this is unusual turn to Page 0, 24 to make sure that we have defined this is	in some way.
Page 15	Page 17
1 if you would. 1 So that which it wasn't. Like, in 2010	-
2 A. Okay. Is it 0, like, right there? 2 really very little definition. Certainly in	
3 Q. No, it's not the first page. The first 3 there was almost no definition.	
5 Q. No, it's not the first page. The first 5 there was almost no definition.	
4 page of text is labeled 0. 4 Q. And are you prepared to testify t	that, as of
4 page of text is labeled 0. 4 Q. And are you prepared to testify t	that are
4 page of text is labeled 0.4Q. And are you prepared to testify the formation of the format	that are
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 4 Q. And are you prepared to testify the second second	that are good
4 page of text is labeled 0.4Q. And are you prepared to testify the first paragraph, this5A. Oh, I see. You go past the Roman numerals?5today, that clinical practice guidelines the first paragraph, this6Okay. Got it.6being created recently are uniformly of the first paragraph, this7Q. And there, in the first paragraph, this79quality?	that are good good
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 4 Q. And are you prepared to testify the first paragraph, this 8 document has a little subsection headed "Purpose of 4 Q. And are you prepared to testify the first paragraph, this 8 A. No. They're still not of uniform 	that are good good to a
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 4 Q. And are you prepared to testify the total practice guidelines the total practice gui	that are good to a se of one
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 4 Q. And are you prepared to testify the total practice guidelines to today, that clinical practice guidelines to today, that clinical practice guidelines to today. And are you prepared to testify the total practice guidelines to today. And are you prepared to testify the total practice guidelines to today. And are you prepared to testify the total practice guidelines to total practice guidelines are, quote, 4 Q. And are you prepared to testify the total practice guidelines to total practice guidelines are, quote, 4 Q. And are you prepared to testify the total practice guidelines to total practice guidelines are, quote, 4 Q. And are you prepared to testify the total practice guidelines to total practice guidelines are, quote, 4 Q. And are you prepared to testify the total practice guidelines to total practice guidelines are, quote, 5 today, that clinical practice guidelines are, quote, 6 being created recently are uniformly of the total practice guidelines are, quote, 7 quality. But I think they're being held to the total practice guidelines are, quote, 	that are good good to a se of one hodology
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 4 Q. And are you prepared to testify the total practice guidelines are of the total practice guideline with a mether of the total producing the guideline. And the total practice guideline with a mether of the total practice of the total practice guideline with a mether of the total practice of the total	that are good to a se of one hodology hat wasn't the
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 4 Q. And are you prepared to testify the total practice guidelines are, quote, 11 "boyou see that? 4 Q. And are you prepared to testify the total practice guidelines are, quote, 11 "boyou see that? 4 Q. And are you prepared to testify the total practice guidelines are, quote, 11 "boyou see that? 4 Q. And are you prepared to testify the total practice guidelines are, quote, 14 Do you see that? 4 Q. And are you prepared to testify the total practice guidelines are, quote, 14 Q. During those many years, on when the total practice guideline with a mether total producing the guideline. And the total producing the guideline with a mether total producing the guideline. And the total producing the guideline. And the total producing the guideline with a mether total producing the guideline. And the total producing the guideline. An	that are good good to a se of one hodology hat wasn't the
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 4 Q. And are you prepared to testify the total practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 14 Do you see that? 15 A. Yes, I do. 4 Q. And are you prepared to testify the total practice guidelines are, quote, 11 "systematically developed statements to assist 12 behind producing the guideline. And the total producing the guideline. And the total	that are good good to a se of one hodology hat wasn't the
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 14 Do you see that? 15 A. Yes, I do. 4 Q. And are you prepared to testify the total practice guidelines are, quote, 14 Do you see that? 15 A. Yes, I do. 4 Q. And are you prepared to testify the total practice guidelines are, quote, 14 Do you see that? 15 A. Yes, I do. 16 Q. And is it consistent with your 4 Q. And are you prepared to testify the total practice guideline with your 4 Q. And are you prepared to testify the total practice guidelines created, if not using a system 16 Do you see that? 16 Q. And is it consistent with your 	that are good good to a se of one hodology hat wasn't the nat basis were natic
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 14 Do you see that? 15 A. Yes, I do. 16 Q. And is it consistent with your 17 understanding that the purpose of clinical practice 	that are 'good good to a se of one hodology hat wasn't the nat basis were natic
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 14 Do you see that? 15 A. Yes, I do. 16 Q. And is it consistent with your 17 understanding that the purpose of clinical practice 18 guidelines is to assist practitioner and patient 	that are ² good good to a se of one hodology hat wasn't the nat basis were natic l school ras expert
 4 page of text is labeled 0. 5 A. Oh, I see. You go past the Roman numerals? 6 Okay. Got it. 7 Q. And there, in the first paragraph, this 8 document has a little subsection headed "Purpose of 9 the AGREE II Instrument." And that indicates that 10 clinical practice guidelines are, quote, 11 "systematically developed statements to assist 12 practitioner and patient decisions about appropriate 13 health care for specific clinical circumstances." 14 Do you see that? 15 A. Yes, I do. 16 Q. And is it consistent with your 17 understanding that the purpose of clinical practice 18 guidelines is to assist practitioner and patient 19 decisions? 4 Q. And are you prepared to testify the study of the distribution of the study of the distribution of the dist	that are good good to a se of one hodology hat wasn't the nat basis were natic l school vas expert se best way to
4page of text is labeled 0.4Q. And are you prepared to testify to5A. Oh, I see. You go past the Roman numerals?5today, that clinical practice guidelines to6Okay. Got it.5today, that clinical practice guidelines to7Q. And there, in the first paragraph, this6being created recently are uniformly of8document has a little subsection headed "Purpose of8A. No. They're still not of uniform9the AGREE II Instrument." And that indicates that9quality. But I think they're being held to10clinical practice guidelines are, quote,10different standard. There is now a sense11"systematically developed statements to assist11needs to go into a guideline with a meth12practitioner and patient decisions about appropriate12behind producing the guideline. And the13health care for specific clinical circumstances."14Q. During those many years, on wh15A. Yes, I do.15guidelines is to assist practitioner and patient16Q. And is it consistent with your16methodology?17understanding that the purpose of clinical practice17A. So in I mean, I was in medical18guidelines is to assist practitioner and patient18from 1991 to 1995, and best practice was19decisions?20do it," and everyone said "Okay." And	that are good good to a se of one hodology hat wasn't the nat basis were natic l school ras expert te best way to we really
4page of text is labeled 0.4Q. And are you prepared to testify to5A. Oh, I see. You go past the Roman numerals?6Okay. Got it.7Q. And there, in the first paragraph, this6being created recently are uniformly of8document has a little subsection headed "Purpose of8A. No. They're still not of uniform9the AGREE II Instrument." And that indicates that9quality. But I think they're being held to10clinical practice guidelines are, quote,10different standard. There is now a sense11"systematically developed statements to assist11needs to go into a guideline. And the12practitioner and patient decisions about appropriate12behind producing the guideline. And the13health care for specific clinical circumstances."14Q. During those many years, on wh15A. Yes, I do.15guidelines is to assist practitioner and patient16Q. And is it consistent with your17A. So in I mean, I was in medical17Merstanding that the purpose of clinical practice18from 1991 to 1995, and best practice was19decisions?20A. Yes.2020A. Yes.20do it," and everyone said "Okay." And21Q. And that those are to be systematically21really that's not the way you decide what	that are good good to a se of one hodology hat wasn't the nat basis were natic l school ras expert te best way to we really at is
4page of text is labeled 0.4Q. And are you prepared to testify to5A. Oh, I see. You go past the Roman numerals?6Okay. Got it.7Q. And there, in the first paragraph, this6being created recently are uniformly of8document has a little subsection headed "Purpose of7quality?9the AGREE II Instrument." And that indicates that9quality. But I think they're being held to10clinical practice guidelines are, quote,10different standard. There is now a senson11"systematically developed statements to assist11needs to go into a guideline with a methol12practitioner and patient decisions about appropriate12behind producing the guideline. And the13health care for specific clinical circumstances."14Q. During those many years. So14Do you see that?14Q. During those many years, on wh15A. Yes, I do.16Q. And is it consistent with your16Q. And is it consistent with your16methodology?17understanding that the purpose of clinical practice18from 1991 to 1995, and best practice was19decisions?20A. Yes.2020A. Yes.20do it," and everyone said "Okay." And21Q. And that those are to be systematically22evidence, right? So the concept of evid22developed?20evidence, right? So the concept of evid	that are good good to a se of one hodology hat wasn't the nat basis were natic l school ras expert te best way to we really at is
4page of text is labeled 0.4Q. And are you prepared to testify to5A. Oh, I see. You go past the Roman numerals?6Okay. Got it.7Q. And there, in the first paragraph, this6being created recently are uniformly of8document has a little subsection headed "Purpose of8A. No. They're still not of uniform9the AGREE II Instrument." And that indicates that9quality. But I think they're being held to10clinical practice guidelines are, quote,10different standard. There is now a sense11"systematically developed statements to assist11needs to go into a guideline. And the12practitioner and patient decisions about appropriate12behind producing the guideline. And the13health care for specific clinical circumstances."14Q. During those many years, on wh15A. Yes, I do.15guidelines is to assist practitioner and patient16Q. And is it consistent with your17A. So in I mean, I was in medical17Merstanding that the purpose of clinical practice18from 1991 to 1995, and best practice was19decisions?20A. Yes.2020A. Yes.20do it," and everyone said "Okay." And21Q. And that those are to be systematically21really that's not the way you decide what	that are good good to a se of one hodology hat wasn't the nat basis were natic l school ras expert se best way to we really at is dence-based

1	Page 18 And the second sentence in that third perceraph	1	Page 20 II; am I correct?
	And the second sentence in that third paragraph	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	reads, quote, "To that end, the AGREE instrument is	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. One, two, three, four, five, six, seven,
	a tool that assesses the methodological rigour and		eight, yes.
4	transparency in which a guideline is developed."	4	Q. Okay. And one of those is whether
5	Do you understand the distinction being	5	systematic methods were used to search for evidence,
6	made between methodological rigour and transparency		correct?
	A. Yes.		A. Can I just say, it's a little bit
8	Q. And do you understand those to be two key	8	confusing, to be honest, because it's Number 8 to
9	aspects of an appropriate method of developing a	9	14, so my math tells me it's six. I don't know why
10	guideline?	10	that is.
11	A. So there are two components that need to be	11	Q. It is because of the place that it says
12	considered when developing a guideline, is the way I	12	"New Item 9" is why. So the numbering is messed up.
13	think of it.	13	A. Okay. Okay.
14	Q. Those being rigour and transparency?	14	Q. I had miscounted myself for exactly the
15	A. Methodology, rigour I mean, you could	15	same reason.
16	put those two together, but you need a methodology and you need transparency when you develop a	16	But now we can put the numbering aside,
17		17	perhaps, and one of the criteria for Rigour of
18 19	guideline.	18 19	Development is Line 8, "Systematic methods were use to search for evidence," correct?
	Q. All right. If we look on the second page this is a European document. I see the	20	A. Yes.
20	spelling, and they seem to have numbered their pages	20	
21	like they number the floors on an elevator.	$ ^{21}_{22}$	Q. And one is whether the criteria for selecting the evidence were clearly described,
22 23	So if you look at the second page, numbered		-
23	1, there is table that says, "Comparison of the	23	right? A. Yes.
24	i, there is table that says, Comparison of the	24	A. 163.
1	Page 19	1	Page 21
	Original AGREE and AGREE II items." Do you see	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	Q. Looking at 11, whether the not only the
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	that?	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	health benefits, but side effects and risks have
	A. Yes.		been considered in formulating the recommendations,
4	Q. And down a little more than halfway through	4	8
5	the table is a section headed "Domain 3. Rigour of	5	A. Yes.
6	Development." Do you see that?	6	Q. And whether there Item 12, one of the
7	A. Uh-huh.		criteria of rigour is whether there is an explicit
8	Q. And under that are, in the "AGREE II"		link between the recommendations and the supporting
9	column, seven categories or items that are	9	evidence. Do you see that?
	indicated. Do you see that?	10	A. Yes.
11	A. You're talking in this column here	11	Q. And let me pause on that one for a moment.
12	(indicating)?	12	Why is it important that guidelines provide an
13	Q. Yes.	13	explicit link between the recommendations and the
14	A. Okay.	14	supporting evidence?
15	Q. Just take a moment and look at it. You'll	15	A. I mean, the link might be that there is no
16	see that the first column is "Original AGREE Item,"	16	evidence.
17	and the second is the revised AGREE II set of criteria right?	17	So I guess I'm for me, these are all,
18	criteria, right? A. Yes.	18	frankly, a bit subjective, but you want to be able
19		19	to connect what you're saying as recommendations to what we know or don't know.
20	Q. So back to where we were. "Rigour of	20 21	
21	Development" under the AGREE II column there are		So that is totally reasonable, to say
22	seven specific items under the pardon me. I'm turning over the page. There are eight specific	22 23	there's an explicit link, and the link is simply that there is no evidence. That's the one issue. I
172		· / ٦	
23 24	items under the "Rigour of Development" for AGREE	24	mean, there's lots of issues everybody has with all

1	Page 22	1	Page 24
1	of these things, by the way.	1	A. Yes. But we were, in our guideline,
2	But, yes, you need to be able to say what	2	definitely dealing with a lot that had no evidence
3	recommendations you're making and what evidence	3	behind it.
4	you're using or lack of evidence you're using to	4	So for us these are very you know,
5	support that recommendation.	5	you're sort of doing your best to say, "Okay, here's
6	Q. And in the interests of transparency, you	6	the framework we're trying to work in and how do we
7	need to not only be able to say that, but you need	7	work when there's not much evidence."
8	to say it; am I correct?	8	So what I don't like about Number 12, if
9	MS. LEVI: Object as to form.	9	you want to focus on that, is this concept of
10	A. Yeah, I mean so these are, like these	10	explicity and supporting evidence where, what if
11	are things that they have said, "Gee, it's nice if	11	there is no explicit link, and what if there's no
12	we can do all of this," and you want to be able to	12	supporting evidence.
13	say, in a guideline, did they do something. But I	13	You still could meet the AGREE II criteria.
14	think there's still a lot of you need to sort of	14	You still could explain how you came to your
15	not be able to make such a stand, like, one dominant	15	recommendation.
16	statement that there has to be a link between	16	Q. If you turn to Page Number 2 in the
17	well, I guess I'm not a lawyer.	17	document, there's, towards the bottom, "Domain 6.
18	What I guess what I'm worrying about is	18	Editorial Independence." And the first item there,
19	that one doesn't need to be able to say there's	19	Number 22, is a little differently phrased between
20	supporting evidence. So the whole thing about	20	AGREE and AGREE II.
21	guidelines and where AGREE sort of goes a little bit	21	The AGREE II statement from 2017 says,
22	wrong is that the answer is that part of guidelines	22	quote, "The views of the funding body have not
23	is also identifying big gaps and where we need more	23	influenced the content of the guideline," close
24	evidence.	24	quote.
	Page 23		Page 25
1	Page 23 And so if part of a guideline is to say we	1	Page 25 Do you consider that to be an important
1 2	-	1 2	-
	And so if part of a guideline is to say we		Do you consider that to be an important
2	And so if part of a guideline is to say we don't have any evidence, then how does one make a	2	Do you consider that to be an important criteria for the reliability of a guideline?
23	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation?	2 3	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah.
2 3 4	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation.	2 3 4	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why?
2 3 4 5 6	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these	2 3 4	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of
2 3 4 5 6	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so	2 3 4 5 6	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of
2 3 4 5 6 7	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So	2 3 4 5 6 7	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like
2 3 4 5 6 7 8	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a	2 3 4 5 6 7 8	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we
2 3 4 5 6 7 8 9	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and	2 3 4 5 6 7 8 9	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like
2 3 4 5 6 7 8 9 10	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not.	2 3 4 5 6 7 8 9 10	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay.
2 3 4 5 6 7 8 9 10 11	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear	2 3 4 5 6 7 8 9 10 11	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they
2 3 4 5 6 7 8 9 10 11 12	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's,	2 3 4 5 6 7 8 9 10 11 12	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views
2 3 4 5 6 7 8 9 10 11 12 13	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes.	2 3 4 5 6 7 8 9 10 11 12 13	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know,
2 3 4 5 6 7 8 9 10 11 12 13 14	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a	2 3 4 5 6 7 8 9 10 11 12 13 14	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some
2 3 4 5 6 7 8 9 10 11 12 13 14 15	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a legal document.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some trying to understand.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a legal document. A. Right.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some trying to understand. But there is worry that there's groups that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a legal document. A. Right. Q. And I'm asking questions precisely to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some trying to understand. But there is worry that there's groups that are funding guidelines that would like them to take
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a legal document. A. Right. Q. And I'm asking questions precisely to understand kind of the boundaries of how you as a 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some trying to understand. But there is worry that there's groups that are funding guidelines that would like them to take a certain direction. And so it's just important to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a legal document. A. Right. Q. And I'm asking questions precisely to understand kind of the boundaries of how you as a practitioner understand the document.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some trying to understand. But there is worry that there's groups that are funding guidelines that would like them to take a certain direction. And so it's just important to make sure that whoever is funding the guideline
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a legal document. A. Right. Q. And I'm asking questions precisely to understand kind of the boundaries of how you as a practitioner understand the document. A. Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some trying to understand. But there is worry that there's groups that are funding guidelines that would like them to take a certain direction. And so it's just important to make sure that whoever is funding the guideline isn't actually influencing it, that they're kept
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a legal document. A. Right. Q. And I'm asking questions precisely to understand kind of the boundaries of how you as a practitioner understand the document. A. Okay. Q. And it's indeed how you understood it when 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some trying to understand. But there is worry that there's groups that are funding guidelines that would like them to take a certain direction. And so it's just important to make sure that whoever is funding the guideline isn't actually influencing it, that they're kept totally out of the loop.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	And so if part of a guideline is to say we don't have any evidence, then how does one make a link between that and a recommendation? And you may still need a recommendation. So that's the other thing is, you come up with these questions that you need to be able to answer, and so sometimes there is no evidence there. So Q. You said in your answer, "I'm not a lawyer," and A. No, I'm not. Q just to be clear A. So none of us loves this stuff that's, like, so specific. But, yes. Q. But just to be clear, this is also not a legal document. A. Right. Q. And I'm asking questions precisely to understand kind of the boundaries of how you as a practitioner understand the document. A. Okay. Q. And it's indeed how you understood it when you were embarked on the project we just looked at,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Do you consider that to be an important criteria for the reliability of a guideline? A. Yeah. Q. Why? A. Well, I think there's the way I've always read this, at least, is and it was sort of noticeable that you had this change from 22, like from the original one to 2017. But I think what we get into is you have external groups that would like a guideline on something, and they offer to pay. And so what's sort of noticeable is they went from "editorially independent" into the views of it haven't influenced, which is I don't know, you were sort of and I think there has been some trying to understand. But there is worry that there's groups that are funding guidelines that would like them to take a certain direction. And so it's just important to make sure that whoever is funding the guideline isn't actually influencing it, that they're kept totally out of the loop. Q. Let me ask you to turn to Page Number 20.

7 (Pages 22 - 25)

	Page 26		Page 28
1	you back up to Page 6, you'll see a heading that	1	A. Oh, the NASPGHAN.
2	says "User's Manual." And the next page says	2	Q. NASPGHAN, there we go.
3	"User's Manual: Instructions for Using the AGREE	3	How many projects involved with developing
4	II."	4	clinical practice guidelines have you been
5	Now, whether or not in this form, do you	5	personally involved in in your professional career?
6	believe that you have seen an official set of	6	A. A number. I don't know, actually.
7	instructions for how to apply the AGREE II	7	Q. And in each one of those, there's been a
8	Instrument?	8	methodologist involved you relied on?
9	A. So this probably is the most I've ever	9	A. No.
10	really looked at it.	10	Q. How did you go about it in a case in which
11	Q. But you've seen it before, you think?	11	there was not a methodologist involved, since you
12	A. I've followed a methodologist who probably	12	don't consider yourself to be a methodologist, a
13	was using it.	13	methodology expert?
14	Q. Okay. You don't consider yourself is	14	A. So I've been involved with guidelines since
15	methodologist?	15	2005, maybe was the first one that I got involved
16	A. I'm not a methodologist.	16	with, and there were no methodologists at that time.
17	Q. Can you describe when you distinguish	17	So, you know, it's a new concept, that you would
18	yourself from a methodologist, what is the expertise	18	bring somebody in who doesn't know the content but
19	of a methodologist that you relied on in the course	19	simply is an expert in the methodologies.
20	of your own projects relating to developing	20	Q. Okay.
21	guidelines?	21	At any rate, if you turn to Page 20 now of
22	A. So the methodologist guides the process,	22	the document, and indeed flip through whatever pages
23	and they're making suggestions about what	23	you like, and I think you will see that kind of item
24	methodologies to be used.	24	by item from the table we looked at earlier, there
	Page 27		Page 29
1	Q. In that context, is a methodologist	1	are headings and a ranking table from 1 to 7, and
1 2	Q. In that context, is a methodologist somebody who has special expertise in the process	1 2	are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your
	Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines?	1 2 3	are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly?
2	Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines?A. So, for me, a methodologist is someone	2 3 4	are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes.
23	Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines?A. So, for me, a methodologist is someone who's ready to say that they have delved into this	2 3 4 5	are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly?A. Yes.Q. And are you on numbered Page 20 now?
2 3 4 5 6	Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines?A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken	2 3 4 5 6	are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly?A. Yes.Q. And are you on numbered Page 20 now?A. Yes.
2 3 4 5 6 7	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, 	2 3 4 5 6 7	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of
2 3 4 5 6 7 8	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. 	2 3 4 5 6 7 8	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic
2 3 4 5 6 7 8 9	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think 	2 3 4 5 6 7 8 9	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence."
2 3 4 5 6 7 8 9 10	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE 	2 3 4 5 6 7 8 9 10	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your
2 3 4 5 6 7 8 9 10 11	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? 	2 3 4 5 6 7 8 9 10 11	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who
2 3 4 5 6 7 8 9 10 11 12	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. 	2 3 4 5 6 7 8 9 10 11 12	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a
2 3 4 5 6 7 8 9 10 11 12 13	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and 	2 3 4 5 6 7 8 9 10 11 12 13	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is
2 3 4 5 6 7 8 9 10 11 12 13 14	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step 	2 3 4 5 6 7 8 9 10 11 12 13 14	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. Q as you went? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. Q as you went? A. No. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7? MS. LEVI: I'm going to just let you know,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. Q as you went? A. No. Q. You would talk to a methodologist? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7? MS. LEVI: I'm going to just let you know, you can take the time that you need to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. Q as you went? A. No. Q. You would talk to a methodologist? A. Yes. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7? MS. LEVI: I'm going to just let you know, you can take the time that you need to THE WITNESS: Look at what's happening
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. Q as you went? A. No. Q. You would talk to a methodologist? A. Yes. Q. Okay. Then all I can do is ask for your 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7? MS. LEVI: I'm going to just let you know, you can take the time that you need to THE WITNESS: Look at what's happening here.
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. Q as you went? A. No. Q. You would talk to a methodologist? A. Yes. Q. Okay. Then all I can do is ask for your understanding as a result of having done that on 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7? MS. LEVI: I'm going to just let you know, you can take the time that you need to THE WITNESS: Look at what's happening here. MR. BROOKS: Absolutely.
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\end{array} $	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. Q as you went? A. No. Q. You would talk to a methodologist? A. Yes. Q. Okay. Then all I can do is ask for your understanding as a result of having done that on the how did you pronounce that bunch of letters? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7? MS. LEVI: I'm going to just let you know, you can take the time that you need to THE WITNESS: Look at what's happening here. MR. BROOKS: Absolutely. MS. LEVI: look at this before you answer
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	 Q. In that context, is a methodologist somebody who has special expertise in the process for developing guidelines? A. So, for me, a methodologist is someone who's ready to say that they have delved into this and really worked on it. Some people have taken courses. Some people haven't. There's no, like, degree in methodology that I know of. Q. So when you say "delved into this," I think you were gesturing, like, the details of the AGREE Instrument, correct? A. Into, yes, the very specific words. Q. And that's not you. You didn't go and consult the document step by step A. No. Q as you went? A. No. Q. You would talk to a methodologist? A. Yes. Q. Okay. Then all I can do is ask for your understanding as a result of having done that on 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 are headings and a ranking table from 1 to 7, and then a discussion of how you would arrive at your ranking. Am I describing it fairly? A. Yes. Q. And are you on numbered Page 20 now? A. Yes. Q. This is under the heading "Rigour of Development," and the Subpoint 7, "Systematic methods were used to search for evidence." And is it consistent with your understanding that, at least in concept, a user who wants to use the AGREE II instrument to evaluate a set of clinical practice guidelines would be is essentially asked by the AGREE II instrument to go through each one of these items and assign a rating between 1 and 7? MS. LEVI: I'm going to just let you know, you can take the time that you need to THE WITNESS: Look at what's happening here. MR. BROOKS: Absolutely.

8 (Pages 26 - 29)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 10 of 58

CONFIDENTIAL

	Page 30		Page 32
1	looking	1	provided including search terms used, sources
2	MS. LEVI: Flip through the document. Take	2	consulted, and dates of the literature covered."
3	whatever time you need to familiarize yourself.	3	Do you see that?
4	THE WITNESS: I appreciate that.	4	A. Yes.
5	MS. LEVI: Yeah. Of course.	5	Q. And is that something that your team did
6	A. Okay. So ask the question and let me see	6	when you published your NASPGHAN guidelines?
7	if I can understand what I'm looking at to answer	7	A. Yes.
8	it, maybe.	8	Q. And why did you consider that to be
9	Q. You earlier described the kind of primary	9	important information to disclose to the user
10	function of AGREE II as a tool to evaluate a set of	10	community?
11	guidelines after it's been created?	11	MS. LEVI: Object as to form.
12	A. Yes.	12	A. Right. So I think one needs to make sure,
13	Q. And you mentioned that your team on the	13	when you develop a guideline, that you explain how
14	NASPGHAN project had said, "Well, let's keep those	14	you searched for evidence.
15	criteria in view as we do it, rather than only	15	I will tell you, what stood out to me
16	afterwards," right?	16	immediately in this sentence is I think there's
17	A. Yeah. And actually, I will say it was	17	supposed to be a comma after "provided." So these
18	on Page 0. It says it provides a methodological	18	are just I mean, lots of people have lots of
19	strategy for the development of guidelines. So	19	different ways of searching for evidence, so there's
20	that's the way we chose to use AGREE II.	20	lots of ways you could explain what you did.
21	Q. Perfect. And my question is, as we look at	21	And if you're going to do A there's a
22	Page 20, or indeed a number of pages here, is it	22	lot of "mays" in the rest of this paragraph, but if
23	consistent with your understanding that this is	23	you are going to do some sort of electronic
24	designed for a user who is attempting to evaluate a	24	searching, then, yes, you're going to use very
	Page 31		Page 33
1	set of guidelines to, on a point-by-point basis,	1	specific search terms.
2	assign a rating, a strength rating between 1 and 7,	2	It's possible you don't have an electronic
3	and there is discussion that tells you how to go	3	database of what you're looking for, so you'd still
4	about deciding that strength rating?	4	be able to explain that. The important thing is to
5	A. What I will say, looking at it, obviously	5	explain what strategy you used to search for
6	again, and remembering working with it, is one needs	6	evidence.
7		7	Q. And have you made any effort to determine
8	then they're attempting to at least give you how you	8	whether, in connection with the SOC-8 guidelines,
9	want to think about that Likert scale; so, you know,	9	WPATH disclosed search terms or information
10	what you should look at and how to rate it and, you	10	sufficient to replicate the searches done?
11	know, what you're considering. And then honestly,	11	A. Have I made efforts? Can you explain what
12	in the end, you're going to use your best gut you	12	you mean by that. I read the website.
13		13	Q. Do you know whether WPATH, in connection
114	know, your judgment on where you're going to rank	14	with COC 9 displaced seems terms on other
14	them between 1 and 7.	14	with SOC-8, disclosed search terms or other
15	them between 1 and 7. Q. So I think I'm learning a fancy technical	15	information sufficient to replicate the searches
15 16	them between 1 and 7.Q. So I think I'm learning a fancy technical term for rating something between 1 and 7.	15 16	information sufficient to replicate the searches they did for evidence?
15 16 17	them between 1 and 7.Q. So I think I'm learning a fancy technical term for rating something between 1 and 7.Likert	15 16 17	information sufficient to replicate the searchesthey did for evidence?A. So I read the website. I haven't, like
15 16 17 18	them between 1 and 7.Q. So I think I'm learning a fancy technical term for rating something between 1 and 7.LikertA. Likert scale.	15 16 17 18	information sufficient to replicate the searchesthey did for evidence?A. So I read the website. I haven't, likeand then I'm trying to remember it. But I have
15 16 17 18 19	 them between 1 and 7. Q. So I think I'm learning a fancy technical term for rating something between 1 and 7. Likert A. Likert scale. Q. He gets credit for that, huh? 	15 16 17 18 19	information sufficient to replicate the searchesthey did for evidence?A. So I read the website. I haven't, likeand then I'm trying to remember it. But I havememory that they explained how they went looking for
15 16 17 18 19 20	 them between 1 and 7. Q. So I think I'm learning a fancy technical term for rating something between 1 and 7. Likert A. Likert scale. Q. He gets credit for that, huh? The beginning of the discussion under 	15 16 17 18 19 20	information sufficient to replicate the searchesthey did for evidence?A. So I read the website. I haven't, likeand then I'm trying to remember it. But I havememory that they explained how they went looking fortheir evidence, and also they had moments when they
15 16 17 18 19 20 21	 them between 1 and 7. Q. So I think I'm learning a fancy technical term for rating something between 1 and 7. Likert A. Likert scale. Q. He gets credit for that, huh? The beginning of the discussion under "User's Manual Description" on Page 20, and we're in 	15 16 17 18 19 20 21	information sufficient to replicate the searchesthey did for evidence?A. So I read the website. I haven't, likeand then I'm trying to remember it. But I havememory that they explained how they went looking fortheir evidence, and also they had moments when theyknew there wasn't evidence. So they were making
15 16 17 18 19 20 21 22	 them between 1 and 7. Q. So I think I'm learning a fancy technical term for rating something between 1 and 7. Likert A. Likert scale. Q. He gets credit for that, huh? The beginning of the discussion under "User's Manual Description" on Page 20, and we're in Subheading 7, "Systematic methods were used to 	15 16 17 18 19 20 21 22	 information sufficient to replicate the searches they did for evidence? A. So I read the website. I haven't, like and then I'm trying to remember it. But I have memory that they explained how they went looking for their evidence, and also they had moments when they knew there wasn't evidence. So they were making decisions along the way of what to do if there was
15 16 17 18 19 20 21	 them between 1 and 7. Q. So I think I'm learning a fancy technical term for rating something between 1 and 7. Likert A. Likert scale. Q. He gets credit for that, huh? The beginning of the discussion under "User's Manual Description" on Page 20, and we're in Subheading 7, "Systematic methods were used to search for evidence," the text reads, "Details of 	15 16 17 18 19 20 21	information sufficient to replicate the searchesthey did for evidence?A. So I read the website. I haven't, likeand then I'm trying to remember it. But I havememory that they explained how they went looking fortheir evidence, and also they had moments when theyknew there wasn't evidence. So they were making

9 (Pages 30 - 33)

	Page 34		Page 36
1	with SOC-8, disclosed search terms used?	1	Page 21, and this, still under "Rigour of
2	A. So I don't know.	2	Development," is a new criteria that states, quote,
3	Q. And do you know whether they disclosed	3	"The criteria for selecting the evidence are clearly
4	enough information of any type to replicate searches	4	described," close quote.
5	that they did for relevant evidence?	5	And there the first sentence reads, quote,
6	A. My memory is that it was a transparent,	6	"Criteria for including/excluding evidence
7	rigorous process, where they explained how they	7	identified by the search should be provided. These
8	searched for evidence. I don't remember looking or	8	criteria should be explicitly described and reasons
9	understanding if they had specified the search terms	9	for including and excluding evidence should be
10	on the website, is the truth. I don't remember that.	10	clearly stated."
11	But they explained how they did systematic	11	Do you have any knowledge as to whether, in
12	literature reviews, in my memory.	12	connection with any aspect of SOC-8, WPATH disclosed
13	Q. The second sentence reads, "Sources may	13	the criteria it used for including or excluding
14	include electronic databases," and then it lists	14	evidence?
15	some examples, "databases of systematic reviews," it	15	A. We're not looking at the website, but my
16	lists the example of the Cochrane Library and DARE,	16	only memory is that it seemed like a very reasonable
17	"handsearching journals," and it proceeds.	17	thing that they explained as to how they did their
18	Then it says, in the final sentence, "The	18	search, including the inclusion/exclusion criteria.
19	search strategy should be as comprehensive as	19	Q. Do you have any recollection that they
20	possible and executed in a manner free from	20	provided any inclusion or exclusion criteria?
21	potential biases and sufficiently detailed to be	21	A. So I know, or my memory and, again, this
22	replicated."	22	is, for me, common in pediatrics and even common in
23	And, again, I want to ask you whether you	23	what I did that they felt there weren't many
24	know whether, in any context relating to SOC-8,	24	randomized controlled trials. So they were not
	Page 35		Page 37
1	WPATH disclosed how it conducted its searches with	1	going to be limiting things to just randomized
2	sufficient detail to be replicated.	2	controlled trials.
3	A. My memory of the website is they explained	3	And then I think this concept of excluding
4	that they did detail you know, they did a	4	articles not written in English, that's pretty
5	systematic literature search and that they explained	5	common for all of us to sort of struggle with, like,
6	how they came up with their evidence. But beyond	6	at what point do you want articles written in other
7		7	languages, or do you just limit it to English-
8	Q. You would agree with me, would you not,	8	speaking publications.
9	that telling the world that you did a systematic	9	MR. BROOKS: Let me ask the reporter to
10	search is a very different thing from describing	10	mark as Exhibit 3 a printout of a web page from the
11	with enough detail to be replicated?	11	WPATH website that says that's entitled
12	A. Not per se. I think you want to explain	12	"methodology for the development of soc8."
13	how you did your search, and ideally somebody can go		(Document marked as Lightdale
14	and do the search and feel that you found the same	14	Exhibit 3 for identification)
15	evidence, but I think you know, what is that?	15	Q. Obviously I'm showing you paper rather than
	-		the screen.
16	What is sufficiently detailed?	16	
17	What is sufficiently detailed? To me, again, there's a lot still that's	17	A. I appreciate that.
17 18	What is sufficiently detailed? To me, again, there's a lot still that's very sort of, you know, subjective. And that is why	17 18	A. I appreciate that.Q. Did you, in fact well, let me ask first,
17 18 19	What is sufficiently detailed? To me, again, there's a lot still that's very sort of, you know, subjective. And that is why I think, in the end, this description is giving us	17 18 19	A. I appreciate that.Q. Did you, in fact well, let me ask first,would you look through this and see whether this
17 18 19 20	What is sufficiently detailed? To me, again, there's a lot still that's very sort of, you know, subjective. And that is why I think, in the end, this description is giving us how to do this. But you're in the end, there's a	17 18 19 20	A. I appreciate that.Q. Did you, in fact well, let me ask first, would you look through this and see whether this appears to be a printout of the WPATH methodology
17 18 19 20 21	What is sufficiently detailed? To me, again, there's a lot still that's very sort of, you know, subjective. And that is why I think, in the end, this description is giving us how to do this. But you're in the end, there's a Likert scaling, and you're going to use your best	17 18 19 20 21	A. I appreciate that.Q. Did you, in fact well, let me ask first,would you look through this and see whether this appears to be a printout of the WPATH methodology web page that you mentioned a moment ago.
17 18 19 20 21 22	What is sufficiently detailed? To me, again, there's a lot still that's very sort of, you know, subjective. And that is why I think, in the end, this description is giving us how to do this. But you're in the end, there's a Likert scaling, and you're going to use your best judgment on whether somebody did something in a	17 18 19 20 21 22	 A. I appreciate that. Q. Did you, in fact well, let me ask first, would you look through this and see whether this appears to be a printout of the WPATH methodology web page that you mentioned a moment ago. A. Yes, in the sense that it looks really
17 18 19 20 21	What is sufficiently detailed? To me, again, there's a lot still that's very sort of, you know, subjective. And that is why I think, in the end, this description is giving us how to do this. But you're in the end, there's a Likert scaling, and you're going to use your best	17 18 19 20 21	A. I appreciate that.Q. Did you, in fact well, let me ask first,would you look through this and see whether this appears to be a printout of the WPATH methodology web page that you mentioned a moment ago.

10 (Pages 34 - 37)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 12 of 58

CONFIDENTIAL

1	Page 38	1	Page 40
	Q. You do. But let's focus on the text and		associated text, to evaluate any disclosures that
2	see whether if you keep going, you'll get to	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	may have been made in the guideline itself?
	text.		A. I didn't look at the SO I didn't look at
4	A. Okay. Yes.	4	the guideline.
5	Q. "Yes," this looks like what you recall	5	Q. Okay.
6	looking at?	6	If you turn in the AGREE II document,
	A. Yeah.	7	Exhibit 2, I think that was
8	Q. And how long did you spend well, did you	8	A. Yeah.
9	print this out and study it on paper?	9	MS. LEVI: Take your time.
10	A. No.	10	Q to Page 22, at the beginning now
11	Q. You just looked at it on the screen?	11	we're under a new heading here, quote, "The
12	A. Yes.	12	strengths and limitations of the body of evidence
13	Q. And for about how long did you study that	13	are clearly described," close quote.
14	on the screen?	14	And the first sentence there under "User's
15	A. I mean, you had to open up each of those	15	Manual Description" reads, "Statements highlighting
16	boxes and sort of look at things, but probably an	16	the strengths and limitations of the evidence should
17	hour maximum.	17	be provided." And then it continues, "This ought to
18	Q. Okay. Would you point me to anything in	18	include explicit descriptions - using informal or
19	this WPATH web page methodology that either	19	formal tools/methods - to assess and describe the risk of bias for individual studies and/or for
20	discloses or talks about disclosing criteria for	20	
21	inclusion or exclusion of evidence.	21	specific outcomes and/or explicit commentary of the
22	A. Okay. So let me take a minute to see.	22	body of evidence aggregated across all studies."
23 24	Q. Take your time.	23 24	Do you see that? A. Yes.
24	A. (Reviewing document) Yeah, no. So	24	A. 165.
	D 20		
1	Page 39	1	Page 41
1	basically what they are saying it's right here is	1	Q. Can you describe for me what is meant,
2	basically what they are saying it's right here is where they're really talking about their systematic	2	Q. Can you describe for me what is meant, within medical science, by risk of bias associated
23	basically what they are saying it's right here is where they're really talking about their systematic review.	2 3	Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study?
2 3 4	basically what they are saying it's right here iswhere they're really talking about their systematicreview.Q. You're looking at page numbered, in the	2 3 4	Q. Can you describe for me what is meant,within medical science, by risk of bias associatedwith a study?A. So all studies have some bias in them
2 3 4 5	basically what they are saying it's right here iswhere they're really talking about their systematicreview.Q. You're looking at page numbered, in thelower right-hand corner, 6 out of 10?	2 3 4 5	Q. Can you describe for me what is meant,within medical science, by risk of bias associatedwith a study?A. So all studies have some bias in themthat's what you learn in the responsible conduct of
2 3 4 5 6	basically what they are saying it's right here is where they're really talking about their systematic review.Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10?A. Yes.	2 3 4 5	Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study?A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider
2 3 4 5 6 7	basically what they are saying it's right here is where they're really talking about their systematic review.Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10?A. Yes.Q. And 2.4.2?	2 3 4 5 6 7	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way.
2 3 4 5 6 7 8	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. 	2 3 4 5 6 7 8	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're
2 3 4 5 6 7 8 9	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in 	2 3 4 5 6 7 8 9	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II
2 3 4 5 6 7 8 9 10	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion 	2 3 4 5 6 7 8 9 10	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking
2 3 4 5 6 7 8 9 10 11	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? 	2 3 4 5 6 7 8 9 10 11	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way
2 3 4 5 6 7 8 9 10 11 12	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was 	2 3 4 5 6 7 8 9 10 11 12	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at.
2 3 4 5 6 7 8 9 10 11 12 13	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were 	2 3 4 5 6 7 8 9 10 11 12 13	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in
2 3 4 5 6 7 8 9 10 11 12 13 14	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what 	2 3 4 5 6 7 8 9 10 11 12 13 14	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into more of, like, a GRADE process, if you will, where 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by "bias" in that answer.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into more of, like, a GRADE process, if you will, where they're specifying the population, et cetera, PICO 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by "bias" in that answer. A. Well, I mean, "bias" is a big word, and
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into more of, like, a GRADE process, if you will, where they're specifying the population, et cetera, PICO questions. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by "bias" in that answer. A. Well, I mean, "bias" is a big word, and it's not something I personally I mean, I just
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into more of, like, a GRADE process, if you will, where they're specifying the population, et cetera, PICO questions. And I do not see in this piece of text that 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by "bias" in that answer. A. Well, I mean, "bias" is a big word, and it's not something I personally I mean, I just walk around with my own head where we all have
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into more of, like, a GRADE process, if you will, where they're specifying the population, et cetera, PICO questions. And I do not see in this piece of text that they talk inclusion/exclusion criteria. They say 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by "bias" in that answer. A. Well, I mean, "bias" is a big word, and it's not something I personally I mean, I just walk around with my own head where we all have unconscious ways of thinking about things. And then
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into more of, like, a GRADE process, if you will, where they're specifying the population, et cetera, PICO questions. And I do not see in this piece of text that they talk inclusion/exclusion criteria. They say they conduct their systematic reviews. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by "bias" in that answer. A. Well, I mean, "bias" is a big word, and it's not something I personally I mean, I just walk around with my own head where we all have unconscious ways of thinking about things. And then sometimes, especially in medicine, there can be very
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 basically what they are saying it's right here is where they're really talking about their systematic review. Q. You're looking at page numbered, in the lower right-hand corner, 6 out of 10? A. Yes. Q. And 2.4.2? A. 2.4 it's 2.4.1 and 2.4.2. Q. All right. And my question is, where in this document does it discuss criteria for inclusion and exclusion of studies? A. Yeah. So it looks like what they did was they went through a prior guideline, and they were identifying what needed to be updated and then what needed new recommendations and where were systematic reviews required. And they basically then move into more of, like, a GRADE process, if you will, where they're specifying the population, et cetera, PICO questions. And I do not see in this piece of text that they talk inclusion/exclusion criteria. They say 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 Q. Can you describe for me what is meant, within medical science, by risk of bias associated with a study? A. So all studies have some bias in them that's what you learn in the responsible conduct of research training and it is important to consider studies that way. And in this case they're saying they're asking this particular item on the AGREE II framework says, when you did your process of looking at the evidence, that you have come up with some way of assessing bias in each study that you looked at. Q. I think in that answer, and therefore in the field, you use "bias" in a way that perhaps is a little different from the layman's understanding of "bias." Can I ask you to explain what you meant by "bias" in that answer. A. Well, I mean, "bias" is a big word, and it's not something I personally I mean, I just walk around with my own head where we all have unconscious ways of thinking about things. And then

11 (Pages 38 - 41)

1	Page 42		Page 44
1	So you have to be looking at a study to		it?
2	understand whether it was designed in a way to	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. (Reviewing document) Well, I mean, what I
3	ideally account for the fact that there's bias.	3	can tell you is that they presented evidence tables,
4	And then when you write a guideline, you're	4	so I would need to understand what's in the evidence
5	going to be thinking about or you're trying to	5	table. But presumably part of the evidence table is
6	assess evidence, assess a study, you're trying to	6	how strong was the evidence, and bias takes away
7	say, "Okay, how would I rate this bias and/or think	7	from strength.
8	about this bias?"	8	Q. So do you have an understanding of what an
9	And, again, for AGREE, bringing it back to	9	evidence table is?
10	this, you would want to have a way that you went	10	A. I mean, in the abstract. Like, tables can
11	through your evidence and you said, every study,	11	look lots of different ways.
12	"Okay, this is what I found, but what was the risk	12	Q. But explain to me in the abstract what an
13	of bias in the study?"	13	evidence table is.
14	So there are usually worksheets you're	14	A. So, evidence tables and actually, I
15	working through as you look through every piece of	15	think somewhere I just read they've been commenting
16	evidence, or something like that, that lets you	16	on this they can look lots of different ways.
17	systematically say what the bias is.	17	But it's a way of explaining what you looked at that
18	Q. And in this context, bias isn't limited to situations in which isn't limited to the issue of	18	you're saying is your evidence for what you're going
19		19	to make a statement about.
20	humans who are involved wanting one result or	20	Q. And did your NASPGHAN team publish, make
21	another; it can also include an experimental design	21	available to the user community, evidence tables
22 23	that just skews results, can it not?	22	relating to those guidelines?
23	A. Bias can, yeah, be a lot of different things.	23 24	A. So we put a lot of appendices on. So we filled out a lot of different worksheets as we read
24	-	24	find out a fot of different worksheets as we read
	Page 43		Page 45
1	Q. It doesn't necessarily imply any conscious		every paper. I mean, everybody was assigned
2	intent on the part of the people involved in the	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	different things to read, and then you had to sort
3	experiment?		of start to build it up and put it more and more
4	A. Yes. Bias can be both, I mean, conscious	4	synthesized together.
5	and unconscious. It can happen accidentally,	5	So, yes, along the way there are different
6	systematic bias, built in.	6	tables that give evidence for each recommendation.
7	Q. You can have an experimental structure		Q. Things that, to your mind, fall within the
8	which results in false positives, and that would	8	general description of evidence tables?
9	create a risk of bias?	9	A. Again, evidence tables are it's kind of
10	A. Or false negatives.	10	a vague concept in the sense that there are so many
11	Q. Or false negatives.	11	different ways you can lay out what your evidence
12	A. Absolutely.	12 13	is. But, yes.
13	Q. Okay. I just wanted to make sure we didn't	13	Q. And I'm not asking about a specific format.A. Yeah.
14	misunderstand it as a layman might ordinarily understand "bias."	14	Q. I think you've described the flexibility of
15	A. Okay.	15	that.
10	A. Okay.Q. Do you know whether, in connection with any	17	Do you have any knowledge why is it
18	of the recommendations in SOC-8, WPATH disclosed or	18	important, putting aside format, to publish, to make
10	provided any description of risk of bias of studies	19	available to the user community evidence tables
20	that it relied on?	20	presenting the evidence that you that underlie
20	A. I didn't look at the guideline, so I can't	20	your guidelines?
21	comment on that.	$\begin{vmatrix} 21\\22 \end{vmatrix}$	A. Well, I mean, I think it is important, when
1 44			
	O. And nothing in the methodology web page	23	Vou dut out again, ints may be where we are now
23	Q. And nothing in the methodology web page that you looked at told you about that either, did	23 24	you put out again, this may be where we are now in 2024, but when you put out a recommendation on

12 (Pages 42 - 45)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 14 of 58

CONFIDENTIAL

1	Page 46 how to practice medicine, you want to be able to say	1	Page 48 Q. A financial interest?
		2	A. Yeah, sure. That's a better word.
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	that your recommendation is backed up by		
	different you know, ideally different studies or	3	Q. I think that term gets used in various of
4	at least different findings that would make up your	4	the documents.
5	recommendations. So	5	Do you have a view as to whether it is, in
6	Q. Is it also important to do that to enable	6	fact, important, as it says here in this first
7	other members of the medical, scientific community	7	paragraph, that, quote, "there should an explicit
8	to evaluate whether they agree or disagree with your	8	statement that the views or interests of the funding
9	treatment of the evidence?	9	body have not influence the final recommendations"?
10	A. Yeah. I think that's part of the	10	And you commented earlier that that language had
11	transparency piece of guidelines.	11	changed.
12	Q. And do you have any knowledge at all as to	12	A. Yeah.
13	whether, in connection with SOC-8, WPATH published		Q. So what's going on there?
14	anything that could be described as evidence tables?	14	A. It has changed. And I think that by the
15	A. I don't know. I don't know.	15	way, this is, again these are things you might
16	Q. Turn with me, if you would, to Page 38.	16	fill out this and you know, every guideline has
17	And this is under heading "Editorial Independence."	17	somebody usually, by the way, it's a group of
18	This is the language we looked at earlier. There it	18	people that are going to use this Likert scale and
19	says, Item 22, "The views of the funding body have	19	then come to consensus around the Likert scale. So
20	not influenced the content of the guideline."	20	there's, you know, even consensus building around,
21	And it says, at the end of the first	21	okay, where do we feel.
22	paragraph there, quote, "There should be an explicit	22	But I think that there has been, as
23	statement that the views or interests of the funding	23	guidelines have become more and more important,
24	body have not influenced the final recommendations,"	24	there has been more pharmaceutical money in the mix
	Page 47		Page 45
1	close quote.	1	and it has become important to make a statement,
2	Do you see that?	2	intriguingly not that you don't have a
3	A. Yes.	3	pharmaceutical company funding you this implies
4	Q. Who funded your NASPGHAN guideline project?	4	you could have a pharmaceutical company funding yo
5	A. It was mostly sweat equity, a lot of	5	but you should explicitly state that that
6	volunteer effort. But there was a little bit of	6	pharmaceutical company did not influence the final
7	funding from both societies.	7	recommendations, which has been an odd thing the
8	Q. And in the case where there is external	8	whole time. Like, looking at it, you're like, "Who
9	funding, do you consider it important an	9	would let a pharmaceutical company influence your
10	important aspect of transparency to disclose	10	final recommendations?" But anyway, I guess you
11	interests of the funding body?	11	need to be able to do that.
12	A. So I think it would depend exactly what the	12	Q. You think such a thing has never happened?
13	external funding is. So you know, I'm just	13	A. They'd like to, but
14	looking at this list, and some of these I would want	14	Q. Do you believe that the language was
15	to know are you know, are very appropriately	15	changed to require an explicit statement these
16	disclosed, and some I don't know if it's as	16	aren't requirements to call for an explicit
17	important. So "Pharmaceutical companies" is the	17	statement precisely to force the participants to
	one that stands out in that list.	18	focus on ensuring that there is no influence from
18		19	the funding body?
	U. And why is that?		
19	Q. And why is that?A. I think a pharmaceutical company has a	20	A. Intriguingly, no. actually. I think what
19 20	A. I think a pharmaceutical company has a	20 21	A. Intriguingly, no, actually. I think what this was saving, and what AGREE II seems to have
19 20 21	A. I think a pharmaceutical company has a I'm going to use a word I shouldn't use vested	21	this was saying, and what AGREE II seems to have
19 20 21 22	A. I think a pharmaceutical company has a I'm going to use a word I shouldn't use vested interest, I think that's the right word, but they	21 22	this was saying, and what AGREE II seems to have done, is allow for pharmaceutical companies to be
19 20 21	A. I think a pharmaceutical company has a I'm going to use a word I shouldn't use vested interest, I think that's the right word, but they have money at stake depending on how a guideline	21	this was saying, and what AGREE II seems to have

13 (Pages 46 - 49)

	Page 50		Page 52
1	disclose that they're involved, it's saying, Okay,	1	is a copy of the report you submitted in this case.
2	you can say that you know, that seems to be okay.	2	A. Yeah.
3	So it's almost allowing for this, as	3	Q. If you would turn to Paragraph 26.
4	opposed to before or whatever. I think before,	4	Let me ask you a quick question. Have you
5	none of us would have thought that this could be	5	served as an expert witness before this case?
6	happening, but So we've moved into, "Well, just	6	A. On a couple of occasions. Not a case like
7	make a disclosure statement about it."	7	this, but, yes.
8	Q. Well, it's not just a disclosure only a	8	Q. All right. And did anybody assist you in
9	disclosure statement, is it, Dr. Lightdale? It	9	preparing your actual written report?
10	calls for an explicit statement that views and	10	A. No.
11	interests of the funding body have not influenced	11	Q. Let me take you to Paragraph 26, and there
12	the final recommendation, correct?	12	you explain what GRADE is, all caps, G-R-A-D-E.
13	A. It's calling for that. It's saying you	13	We'll talk about that a certain amount. And you
14	should make that statement.	14	state that GRADE "is currently the most commonly
15	Q. And that goes beyond disclosure of who the	15	used system for classifying evidence and the
16	funder is?	16	strength of recommendations."
17	A. I mean, it's saying "the funding body." So	17	Do you see that?
18	this particular statement is the funding body,	18	A. Yes.
19	right, that they're asking for.	19	Q. And what is the basis for your assertion in
20	Q. Let me ask you to turn to Page 41, which is	20	your expert report that GRADE is the most commonly
21	headed "Overall Guideline Assessment."	21	used system for classifying evidence?
22	A. Yes.	22	A. Just gut instinct, like what you're hearing
23	Q. And this simply asks the rater, having	23	everyone talking about.
24	completed everything else, to rate the overall	24	Q. Is there any close competition, or is GRADE
	Page 51		Page 53
1	Page 51 quality of this guideline, again from a scale of 1	1	Page 53 really by far the leading methodology used to rate
1 2	-	1 2	
	quality of this guideline, again from a scale of 1		really by far the leading methodology used to rate
2	quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale.	2	really by far the leading methodology used to rate the strength of evidence today?
23	quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has	23	really by far the leading methodology used to ratethe strength of evidence today?A. I would say it's the main way that people
2 3 4	quality of this guideline, again from a scale of 1to 7, which you referred to as a Likert scale.But then it does something else, and it hasa three-level statement. It begins, "I would	2 3 4	really by far the leading methodology used to ratethe strength of evidence today?A. I would say it's the main way that peopleare using or at least that people feel like they
2 3 4 5	quality of this guideline, again from a scale of 1to 7, which you referred to as a Likert scale.But then it does something else, and it hasa three-level statement. It begins, "I wouldrecommend this guideline for use," and then the	2 3 4 5	really by far the leading methodology used to rate the strength of evidence today?A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that.Q. Let me ask you to find Exhibit 1 again.
2 3 4 5 6	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with 	2 3 4 5 6	really by far the leading methodology used to rate the strength of evidence today?A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that.Q. Let me ask you to find Exhibit 1 again.That is the NASPGHAN paper.
2 3 4 5 6 7	quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No."	2 3 4 5 6 7	really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your
2 3 4 5 6 7 8 9 10	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a 	2 3 4 5 6 7 8 9 10	 really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this
2 3 4 5 6 7 8 9 10 11	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? 	2 3 4 5 6 7 8 9	really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you
2 3 4 5 6 7 8 9 10 11 12	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean 	2 3 4 5 6 7 8 9 10 11 12	really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's
2 3 4 5 6 7 8 9 10 11 12 13	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? 	2 3 4 5 6 7 8 9 10 11 12 13	 really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the
2 3 4 5 6 7 8 9 10 11 12 13 14	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not 	2 3 4 5 6 7 8 9 10 11 12 13 14	really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their opinion that the guideline shouldn't be recommended 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent project to develop clinical practice guidelines,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their opinion that the guideline shouldn't be recommended for use. It's letting you say that as an assessor. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent project to develop clinical practice guidelines, your team used the GRADE system to rate the quality
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their opinion that the guideline shouldn't be recommended for use. It's letting you say that as an assessor. MR. BROOKS: All right. Let me ask the 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent project to develop clinical practice guidelines, your team used the GRADE system to rate the quality of the evidence you found?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their opinion that the guideline shouldn't be recommended for use. It's letting you say that as an assessor. MR. BROOKS: All right. Let me ask the reporter to mark as Exhibit 4 the Expert Rebuttal 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent project to develop clinical practice guidelines, your team used the GRADE system to rate the quality of the evidence you found? A. Yes. That's how we chose to rate evidence.
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their opinion that the guideline shouldn't be recommended for use. It's letting you say that as an assessor. MR. BROOKS: All right. Let me ask the reporter to mark as Exhibit 4 the Expert Rebuttal Declaration of Dr. Jenifer Lightdale. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent project to develop clinical practice guidelines, your team used the GRADE system to rate the quality of the evidence you found? A. Yes. That's how we chose to rate evidence. Q. And you, in fact, used the GRADE rating
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their opinion that the guideline shouldn't be recommended for use. It's letting you say that as an assessor. MR. BROOKS: All right. Let me ask the reporter to mark as Exhibit 4 the Expert Rebuttal Declaration of Dr. Jenifer Lightdale. (Document marked as Lightdale 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent project to develop clinical practice guidelines, your team used the GRADE system to rate the quality of the evidence you found? A. Yes. That's how we chose to rate evidence. Q. And you, in fact, used the GRADE rating system at two stages; am I correct? That is, first
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their opinion that the guideline shouldn't be recommended for use. It's letting you say that as an assessor. MR. BROOKS: All right. Let me ask the reporter to mark as Exhibit 4 the Expert Rebuttal Declaration of Dr. Jenifer Lightdale. (Document marked as Lightdale Exhibit 4 for identification) 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent project to develop clinical practice guidelines, your team used the GRADE system to rate the quality of the evidence you found? A. Yes. That's how we chose to rate evidence. Q. And you, in fact, used the GRADE rating system at two stages; am I correct? That is, first you used it I'm looking about an inch and a half
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 quality of this guideline, again from a scale of 1 to 7, which you referred to as a Likert scale. But then it does something else, and it has a three-level statement. It begins, "I would recommend this guideline for use," and then the answers provided are "Yes," "Yes, with modifications," and "No." Do you see that? A. Yes. Q. And do you have an understanding of what a rating of "No" by a rater is supposed to signify? A. I think so. I mean Q. What is it? A it would mean that the rater does not think the guideline should be it's in their opinion that the guideline shouldn't be recommended for use. It's letting you say that as an assessor. MR. BROOKS: All right. Let me ask the reporter to mark as Exhibit 4 the Expert Rebuttal Declaration of Dr. Jenifer Lightdale. (Document marked as Lightdale 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 really by far the leading methodology used to rate the strength of evidence today? A. I would say it's the main way that people are using or at least that people feel like they can say are using the GRADE process. They'll ask if you're following that. Q. Let me ask you to find Exhibit 1 again. That is the NASPGHAN paper. And in this paper we looked at your reference to AGREE there, but in the course of this work I don't mean to make a memory test if you turn to Page 32, there's a discussion of your team's use of GRADE, as well as the AGREE, towards the bottom of the first column. So am I correct that, in your most recent project to develop clinical practice guidelines, your team used the GRADE system to rate the quality of the evidence you found? A. Yes. That's how we chose to rate evidence. Q. And you, in fact, used the GRADE rating system at two stages; am I correct? That is, first

14 (Pages 50 - 53)

	Page 54		Page 56
	low,' 'low,' "moderate," or 'high)," and then a few	1	to make one objection, and clear to you, that in
2	lines down it says, "The GRADE approach was then	2	answering the questions, you are instructed not to
3	used to determine the strength of recommendations as	3	disclose any conversations you've had with counsel.
4	'strong' [or] 'conditional,'" correct?	4	THE WITNESS: Okay. Okay.
5	A. Yes.	5	MS. LEVI: His questions aren't directed
6	Q. So GRADE provides means of rating both the	6	towards that.
7	strength of evidence and the strength of	7	MR. BROOKS: That is correct. I feel
8	recommendations, right?	8	strongly on that point.
9	A. Yes. You can use it that way, yes.	9	Q. Well, since you didn't know it existed, I
10	Q. And your team did use it that way?	10	was going to ask why did you choose simply to rely
11	A. Right.	11	on the web page rather than the appendix that is
12	MR. BROOKS: Okay. Let me ask the reporter	12	more detailed, but the answer is, you didn't know
13	to mark as Exhibit 5 excerpts an excerpt from the	13	the appendix existed?
14	WPATH SOC-8, which is appendices, including Appendix	14	A. Well, I don't remember knowing about that.
15	8 titled "Methodology."	15	But I will tell you, I mostly stuck with what was
16	(Document marked as Lightdale	16	described I was asked, I got a phone call and was
17	Exhibit 5 for identification)	17	asked, could I look at this and make comments, and I
18	Q. Dr. Lightdale, I've got the cover page	18	made some comments based on the web page. So
19	SOC-8 itself is a very long document, and I have not	19	Q. Okay. Let me call your attention to Page
20	put the whole thing in front of you. You will see	20	250 in the methodology appendix that's Exhibit 5,
21	the cover page, the table of contents, and then,	21	and there's a short paragraph headed "Grading of the
22	beginning at Page S247, "Appendix A, Methodology."	22	evidence."
23	A. Okay.	23	A. Okay.
24	Q. And my first question for you is let me	24	Q. And that states, quote, "The Evidence
	Page 55		Page 57
1	ask you to flip through that Appendix A, which is	1	Review Team assigned evidence grades using the GRADE
2	perhaps six pages long, and ask whether you think	2	methodology. The strength of the evidence was
3	you have ever seen this document before.	3	obtained using predefined critical outcomes for each
4	A. Okay. I'll just flip through it. I have	4	question and by assessing the limitations to
5	not looked at it before.	5	individual study qualities/risk of bias,
6	Q. Okay.	6	consistency, directness, precision, and reporting
7	A. I will need to look at it if we're going to	7	bias."
8	start talking about it.	8	Do you see that?
9	MS. LEVI: Take the time you need to look	9	A. Yes.
10	at it.	10	Q. Do you have any knowledge as to whether, in
11	THE WITNESS: Okay. Okay.	11	fact, anybody within the SOC-8 team ever assigned
12	Q. Let me ask you	12	evidence grades to any evidence using the GRADE
13	A. I don't want to start to speed read.	13	methodology?
14	Q. No, that would be ill-advised.	14	A. No. All I have is their instructions.
15	But first, let me ask you this: Did you	15	Q. If the team told the world, in the
16	know that SOC-8 had a methodology appendix as part	16	published appendix, that they assigned evidence
17	of the published standard of care?	17	grades using the GRADE methodology, and in fact they
18	A. No.	18	did not do so, you, as a person with expertise in
19	Q. When you were asked to prepare your report,	19	developing clinical practice guidelines, would
20	somebody directed you to the methodology web page	20	consider that to be quite problematical, would you
21	but not to the methodology appendix?	21	not?
22	A. I mean, I was in the web page. I'm, like,	22	MS. LEVI: Object as to form.
23	going through different	23	A. I'm also feeling like can you repeat the
24	MS. LEVI: And I'm just going to I want	24	question, because I'm trying to focus on what you're
L		1	

15 (Pages 54 - 57)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 17 of 58

CONFIDENTIAL

1	Page 58	1	Page 60
	asking.	1	specifically set out in the GRADE system, correct?
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	Q. If the SOC development team told the world,	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	A. Not per se. There's actually a fair amount
	n their methodology appendix, that they assigned	3	of ways that you can make decisions yourself about how you are going to grade evidence. So and then
	evidence grades using the GRADE methodology and in		
	fact it did not do so, that would cause you serious	5	the strength of recommendations.
	concern as somebody with experience in developing and using clinical practice guidelines, would it	6	And for instance and I'm not, frankly,
	not?	7 8	looking at what you've given me. But, you know, how are you going to decide something is of high
9	A. So as someone who has experience, I can	9	quality? How many how are you going to decide
	ell you that the GRADE methodology can be applied	10	some of this stuff?
	n different ways. So I would have to understand	10	
	nore why someone is telling me that it wasn't done,		And so even the process of putting together a guideline is a certain amount of consensus about
	because there are so many ways to use it. So	12 13	how you're going to use GRADE methodology. So I
13 1	Q. My question is a simple and a hypothetical	13	don't think it's black and white. It's a process
	one.	14	you go through.
16	A. Okay.	16	Q. Is it your testimony, Dr. Lightdale, that
17	Q. If they told the world, "We assigned	10	the GRADE system does not provide black-and-white
	evidence grades using the GRADE methodology," and	18	definitions, textual definitions of very low, low,
	hey simply did not do so, that would cause you	19	medium and high quality evidence?
	serious concern, would it not?	20	A. It gives you that way of ranking your
21	MS. LEVI: Object as to form.	21	evidence. But in terms of what does it mean to be
22	A. I would be mystified why they would do	22	high quality, that can also be, like, decided along
	hat.	23	the way of what we're going to decide is high
24	Q. You wouldn't go so far as saying it would	24	quality evidence. So that is not a highly that's
1 c	Page 59 concern you?	1	Page 61 not a firmly defined thing, high quality evidence.
2	A. Honestly, I'd be more concerned with	2	Q. As you sit here today, you don't recall the
	omebody trying to say that it didn't happen and to	_	e <i>i i i j i i i i i i i i i i</i>
		3	precisely defined meaning of high quality evidence
4 s		3 4	precisely defined meaning of high quality evidence from GRADE?
	ay, "Well, why do you think it didn't happen?"	4	from GRADE?
5 A	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then		from GRADE? A. I think GRADE talks about what can be high
5 A 6 p	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean,	4 5	from GRADE?
5 A 6 p 7 tl	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then	4 5 6	from GRADE?A. I think GRADE talks about what can be high quality evidence, but there are also things that
5 A 6 p 7 tl 8 b	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology	4 5 6 7	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence.
5 A 6 p 7 tl 8 b	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it,	4 5 6 7 8	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled
5 A 6 p 7 tl 8 b 9 a 10	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways.	4 5 6 7 8 9	 from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very
5 A 6 p 7 tl 8 b 9 a 10 11 v	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you	4 5 6 7 8 9 10	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational
5 A 6 p 7 tl 8 b 9 a 10 11 w 12 m	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE	4 5 7 8 9 10 11	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials.
5 A 6 p 7 tl 8 b 9 a 10 11 v 12 n 13 p	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development	4 5 7 8 9 10 11 12	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because
5 A 6 p 7 tl 8 b 9 a 10 11 v 12 n 13 p	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development process, we had to make decisions about how we were	4 5 7 8 9 10 11 12 13	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not
5 A 6 p 7 tl 8 b 9 a 10 11 w 12 n 13 p 14 g 15	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development process, we had to make decisions about how we were going to use GRADE methodology.	4 5 7 8 9 10 11 12 13 14	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not the same evidence or not the same quality. You actually need to be assessing every study, no matter what the design is.
5 A 6 p 7 tl 8 b 9 a 10 11 v 12 n 13 p 14 g 15 16 "	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development process, we had to make decisions about how we were going to use GRADE methodology. So for me it would be someone telling me,	4 5 6 7 8 9 10 11 12 13 14 15	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not the same evidence or not the same quality. You actually need to be assessing every study, no matter
5 A 6 p 7 tl 8 b 9 a 10 11 w 12 n 13 p 14 g 15 16 " 17 k	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development brocess, we had to make decisions about how we were going to use GRADE methodology. So for me it would be someone telling me, Oh, it didn't happen." I'd say, "Well, how do you	4 5 6 7 8 9 10 11 12 13 14 15 16	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not the same evidence or not the same quality. You actually need to be assessing every study, no matter what the design is.
5 A 6 p 7 tl 8 b 9 a 10 11 w 12 n 13 p 14 g 15 16 " 17 k	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development process, we had to make decisions about how we were going to use GRADE methodology. So for me it would be someone telling me, Oh, it didn't happen." I'd say, "Well, how do you know that? You know, why are you saying that?"	4 5 6 7 8 9 10 11 12 13 14 15 16 17	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not the same evidence or not the same quality. You actually need to be assessing every study, no matter what the design is. So, again, high quality is a process to decide something is of high quality when okay. I'll try to stop talking.
5 A 6 p 7 tl 8 b 9 a 10 11 w 12 n 13 p 14 g 15 16 " 17 k 18 T 19 20 s	 ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then out it into use in the sense of I mean, here's whatever. You're using GRADE methodology out it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development process, we had to make decisions about how we were going to use GRADE methodology. So for me it would be someone telling me, Oh, it didn't happen." I'd say, "Well, how do you snow that? You know, why are you saying that?" Chat would be the bigger concern, to be honest. Q. The GRADE system for rating evidence has a pecific set of four levels of strength, correct, as 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not the same evidence or not the same quality. You actually need to be assessing every study, no matter what the design is. So, again, high quality is a process to decide something is of high quality when okay. I'll try to stop talking. There's a lot of ambiguity here.
5 A 6 p 7 tl 8 b 9 a 10 11 w 12 n 13 p 14 g 15 16 " 17 k 18 T 19 20 s 21 d	 ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then out it into use in the sense of I mean, here's whatever. You're using GRADE methodology out it's just a methodology. So now you apply it, und what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development process, we had to make decisions about how we were going to use GRADE methodology. So for me it would be someone telling me, Oh, it didn't happen." I'd say, "Well, how do you cnow that? You know, why are you saying that?" Chat would be the bigger concern, to be honest. Q. The GRADE system for rating evidence has a specific set of four levels of strength, correct, as lescribed in your NASPGHAN document; that is, very 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not the same evidence or not the same quality. You actually need to be assessing every study, no matter what the design is. So, again, high quality is a process to decide something is of high quality when okay. I'll try to stop talking. There's a lot of ambiguity here. Q. Was WPATH's use of the widely accepted
5 A 6 p 7 tl 8 b 9 a 10 11 w 12 n 13 p 14 g 15 16 " 17 k 18 T 19 20 s 21 d 22 lo	ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then but it into use in the sense of I mean, here's whatever. You're using GRADE methodology but it's just a methodology. So now you apply it, and what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development process, we had to make decisions about how we were going to use GRADE methodology. So for me it would be someone telling me, Oh, it didn't happen." I'd say, "Well, how do you know that? You know, why are you saying that?" Chat would be the bigger concern, to be honest. Q. The GRADE system for rating evidence has a specific set of four levels of strength, correct, as lescribed in your NASPGHAN document; that is, very ow, low, moderate or high?	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not the same evidence or not the same quality. You actually need to be assessing every study, no matter what the design is. So, again, high quality is a process to decide something is of high quality when okay. I'll try to stop talking. There's a lot of ambiguity here. Q. Was WPATH's use of the widely accepted GRADE system for classifying the strength of
5 A 6 p 7 tl 8 b 9 a 10 11 w 12 n 13 p 14 g 15 16 " 17 k 18 T 19 20 s 21 d	 ay, "Well, why do you think it didn't happen?" Again, there are so many ways to take GRADE and then out it into use in the sense of I mean, here's whatever. You're using GRADE methodology out it's just a methodology. So now you apply it, und what it looks like can look very different ways. So how we used it in our worksheets, if you will, and how our process worked is, using GRADE methodology as we went through our development process, we had to make decisions about how we were going to use GRADE methodology. So for me it would be someone telling me, Oh, it didn't happen." I'd say, "Well, how do you cnow that? You know, why are you saying that?" Chat would be the bigger concern, to be honest. Q. The GRADE system for rating evidence has a specific set of four levels of strength, correct, as lescribed in your NASPGHAN document; that is, very 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	from GRADE? A. I think GRADE talks about what can be high quality evidence, but there are also things that they know also can be high quality evidence. So the classic is randomized controlled trials can be high quality evidence, but so can very well defined or, you know, designed observational trials. So you can't just say, just because something is an observational trial, that it's not the same evidence or not the same quality. You actually need to be assessing every study, no matter what the design is. So, again, high quality is a process to decide something is of high quality when okay. I'll try to stop talking. There's a lot of ambiguity here. Q. Was WPATH's use of the widely accepted

16 (Pages 58 - 61)

	Page 62		Page 64
1	your expert report that, and I quote, "WPATH's	1	developing and presenting summaries of evidence and
2	method for developing SOC-8 is exemplary," close	2	provides a systematic approach for making clinical
3	quote?	3	practice recommendations," and it cites Guyatt, et
4	A. I made that statement because I was so	4	al., close quote.
5	impressed by how they had spelled out their entire	5	Do you see that?
6	process on the web page for developing their	6	A. Yes.
7	guideline and had really shown it to be very	7	Q. Does the name "Guyatt" mean anything to
8	carefully a priori thought about, it was very	8	you?
9	rigorous, it seemed to me to be very transparent in	9	A. So for me it is a reference that one often
10	what they had done, how they had come up with their	10	uses when you are explaining that you used GRADE.
11	groups, how they'd organized themselves. They gave	11	So, you know, it's a person.
12	a lot of information there that, honestly, most	12	Q. Do you know who Professor Guyatt is?
13	societies aren't doing at this point.	13	A. Not in any meaningful way, no.
14	So it was very impressive how they had	14	Q. Do you know anything about his reputation
15	taken a lot of steps to spell out what they had		in the field of evidence-based medicine?
16	done.	16	A. He is the first author on this sort of
17	Q. Was their use of the widely accepted GRADE	17	important text that you use to say you're using
18	system to rate evidence and the strength of	18	GRADE.
19	recommendations an important part of the basis for	19	Q. You've never heard him speak at a
20	your conclusion that their method for developing	20	conference?
21	SOC-8 was exemplary?	21	A. No. No.
22	A. No. I would say it was more that they said	22	Q. Okay. In your report you mention that some
23	what method that they used.	23	criticisms have been made of the GRADE system of
23	So, you know, I think I mean, again,	23	evaluating the strength of evidentiary support, but
	50, you know, I think T moun, uguni,		evaluating the strength of evidentially support, out
1	Page 63	1	Page 65
	GRADE for me is something common and I sort of had a	1	you, yourself, have recently used GRADE
2	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous	2	you, yourself, have recently used GRADE A. (Nods head)
23	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is.	2 3	you, yourself, have recently used GRADEA. (Nods head)Q and I think you've you have to
2 3 4	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more	2 3 4	you, yourself, have recently used GRADEA. (Nods head)Q and I think you've you have toA. Oh, yes. Sorry.
2 3 4 5	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's	2 3 4 5	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is
2 3 4	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through	2 3 4 5 6	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the
2 3 4 5 6 7	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not	2 3 4 5 6 7	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently.
2 3 4 5	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't	2 3 4 5 6 7 8	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head)
2 3 4 5 6 7 8 9	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the	2 3 4 5 6 7 8 9	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they
2 3 4 5 6 7 8 9 10	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent	2 3 4 5 6 7 8 9 10	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence,
2 3 4 5 6 7 8 9 10 11	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process.	2 3 4 5 6 7 8 9 10 11	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct?
2 3 4 5 6 7 8 9 10 11 12	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've	2 3 4 5 6 7 8 9 10 11 12	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes.
2 3 4 5 6 7 8 9 10 11	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be	2 3 4 5 6 7 8 9 10 11 12 13	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that
2 3 4 5 6 7 8 9 10 11 12 13 14	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this	2 3 4 5 6 7 8 9 10 11 12 13 14	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to
2 3 4 5 6 7 8 9 10 11 12 13 14 15	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay. MR. BROOKS: If you're all right, we'll go	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay. MR. BROOKS: If you're all right, we'll go for a few more minutes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an understanding that nothing's perfect, right?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay. MR. BROOKS: If you're all right, we'll go for a few more minutes. Q. In the second column on Page 250, S250, is	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an understanding that nothing's perfect, right? So and that, by the way, is everything.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay. MR. BROOKS: If you're all right, we'll go for a few more minutes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an understanding that nothing's perfect, right? So and that, by the way, is everything.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay. MR. BROOKS: If you're all right, we'll go for a few more minutes. Q. In the second column on Page 250, S250, is	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an understanding that nothing's perfect, right? So and that, by the way, is everything. That's the evidence we're using to make the guidelines or lack of evidence. That's how we
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay. MR. BROOKS: If you're all right, we'll go for a few more minutes. Q. In the second column on Page 250, S250, is a section "Grading criteria for statements." Do you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an understanding that nothing's perfect, right? So and that, by the way, is everything. That's the evidence we're using to make the guidelines or lack of evidence. That's how we create groups that are going to make the guidelines.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay. MR. BROOKS: If you're all right, we'll go for a few more minutes. Q. In the second column on Page 250, S250, is a section "Grading criteria for statements." Do you see that?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an understanding that nothing's perfect, right? So and that, by the way, is everything. That's the evidence we're using to make the guidelines or lack of evidence. That's how we create groups that are going to make the guidelines.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	GRADE for me is something common and I sort of had a sense of just how much work it is and how rigorous it is. But I think you could I was frankly more impressed with the whole shebang. So for me it's more explaining very clearly how you went through the process of developing your guideline, not necessarily that one used GRADE. Like, that wasn't what made me feel so good about it. It was the whole description of a rigorous and transparent process. MS. LEVI: Roger, I'm just checking. We've been a little over an hour. Would now be MR. BROOKS: Let me I'll wrap up this series of questions shortly. MS. LEVI: Okay. MR. BROOKS: If you're all right, we'll go for a few more minutes. Q. In the second column on Page 250, S250, is a section "Grading criteria for statements." Do you see that? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 you, yourself, have recently used GRADE A. (Nods head) Q and I think you've you have to A. Oh, yes. Sorry. Q. And I think you've testified that it is much the most widely used system for evaluating the strength of evidence currently. A. (Nods head) Q. And as we've seen, WPATH states that they used GRADE to determine the strength of evidence, correct? A. Yes. Q. What was your point in mentioning that GRADE has been criticized? A. Well, I think, as I've been saying, for me this is still an evolution, and I think you have to approach anything we do around guidelines with an understanding that nothing's perfect, right? So and that, by the way, is everything. That's the evidence we're using to make the guidelines or lack of evidence. That's how we create groups that are going to make the guidelines.

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 19 of 58

CONFIDENTIAL

	Page 66		Page 68
1	going to use.	1	So Dr. Guyatt has got some subordinates,
2	And in there is GRADE has emerged as a	2	but he is the senior person on this project?
3	methodology we're all coalesced around, but you know	3	A. (Nods head)
4	that it is not perfect. And I'll say to my own,	4	Q. Do you think that you have ever before
5	there are many different ways you can use it. And	5	today seen and there are, I think, at least 15 in
6	so part of process is even deciding how you're going	6	this numbered sequence. I'm not going to put them
7	to use it, and, you know, there are still a lot of	7	all in front of you, I promise.
8	judgment calls to it.	8	Do you think you have seen any of these
9	So in pursuit of perfection continues, and	9	numbered papers setting out the GRADE system?
10	therefore, criticism is welcome to keep making it	10	A. I don't know that I've ever seen the papers
11	better.	11	specifically before.
12	Q. All right. Well, you've made some	12	Q. Okay. I want to call your attention to
13	criticism of GRADE in your expert report. Let me	13	Page 404, Table 2, which provides statements of the
14	ask you this.	14	meaning of the four levels of evidence. And I'll
15	A. Yes.	15	there are many places I could have gone to show you
16	Q. Have you ever published have you ever,	16	these same definitions. This is just one.
17	in any publication, criticized GRADE in any way?	17	And there's two columns there's three
18	A. No.	18	columns. One is "Quality level," "High,"
19	MR. BROOKS: All right. Let's take a	19	"Moderate," "Low," "Very low." The second column
20	break.	20	says "Current definition." And, again, this paper
21	MS. LEVI: Okay.	21	is as of 2011. And the final column reads "Previous
22	(Recess)	22	definition."
23	MR. BROOKS: Let me ask the reporter to	23	Let me ask you to look at the column that
24	mark as Exhibit 6 an article from 2011 entitled	24	says "Current definition" and tell me whether those
	Page 67		Page 69
			6
1	"GRADE guidelines: 3. Rating the quality of	1	are indeed the definitions of or the statements
1 2	"GRADE guidelines: 3. Rating the quality of evidence."	2	are indeed the definitions of or the statements of the meaning of the quality levels within the
3	"GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale	2 3	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are
34	"GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification)	2 3 4	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with.
3 4 5	"GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS:	2 3 4 5	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks
3 4 5 6	"GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally,	2 3 4 5 6	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with.A. I would have to compare it, but it looks approximately like what we used. In other words,
3 4 5 6 7	"GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series	2 3 4 5 6 7	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for
3 4 5 6 7 8	"GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system?	2 3 4 5 6 7 8	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with.A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit.
3 4 5 6 7 8 9	"GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar.	2 3 4 5 6 7 8 9	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it
3 4 5 6 7 8 9 10	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, 	2 3 4 5 6 7 8 9 10	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate
3 4 5 6 7 8 9 10 11	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. 	2 3 4 5 6 7 8 9 10 11	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially
3 4 5 6 7 8 9 10 11 12	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the 	2 3 4 5 6 7 8 9 10 11 12	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect."
3 4 5 6 7 8 9 10 11 12 13	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last 	2 3 4 5 6 7 8 9 10 11 12 13	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language?
3 4 5 6 7 8 9 10 11 12 13 14	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the 	2 3 4 5 6 7 8 9 10 11 12	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes.
3 4 5 6 7 8 9 10 11 12 13	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? 	2 3 4 5 6 7 8 9 10 11 12 13 14	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes. Q. And do you have an understanding of what
3 4 5 6 7 8 9 10 11 12 13 14 15	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? A. Yes. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes.
3 4 5 6 7 8 9 10 11 12 13 14 15 16	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? A. Yes. Q. What is that? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes. Q. And do you have an understanding of what that means, what it means if you assign that rating
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? A. Yes. Q. What is that? A. So, generally speaking, the last author is 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes. Q. And do you have an understanding of what that means, what it means if you assign that rating to the results of a study?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? A. Yes. Q. What is that? A. So, generally speaking, the last author is your senior person, who then is usually looking at 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes. Q. And do you have an understanding of what that means, what it means if you assign that rating to the results of a study? A. So, yes.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? A. Yes. Q. What is that? A. So, generally speaking, the last author is your senior person, who then is usually looking at the first person those two people are usually the 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes. Q. And do you have an understanding of what that means, what it means if you assign that rating to the results of a study? A. So, yes. Q. What is that understanding?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? A. Yes. Q. What is that? A. So, generally speaking, the last author is your senior person, who then is usually looking at the first person those two people are usually the people who are writing the paper together. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes. Q. And do you have an understanding of what that means, what it means if you assign that rating to the results of a study? A. So, yes. Q. What is that understanding? A. So I think this a lot of this is subjective ratings of evidence. And here, when you when the group decides something's of low
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? A. Yes. Q. What is that? A. So, generally speaking, the last author is your senior person, who then is usually looking at the first person those two people are usually the people who are writing the paper together. Q. Okay. The first person probably did the most work, and the last person is the most senior A. Senior, yes. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes. Q. And do you have an understanding of what that means, what it means if you assign that rating to the results of a study? A. So, yes. Q. What is that understanding? A. So I think this a lot of this is subjective ratings of evidence. And here, when you when the group decides something's of low confidence, or frankly if an individual is doing
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 "GRADE guidelines: 3. Rating the quality of evidence." (Document marked as Lightdale Exhibit 6 for identification) BY MR. BROOKS: Q. And, Dr. Lightdale, let me ask generally, are you familiar with a series a numbered series of papers published that detail the GRADE system? A. I'm familiar. Q. And you'll see there's a number of authors, of which Dr. Guyatt is the last. Are you able to tell me, just for the record, generally what the significance of the last named author is on an academic paper? A. Yes. Q. What is that? A. So, generally speaking, the last author is your senior person, who then is usually looking at the first person those two people are usually the people who are writing the paper together. Q. Okay. The first person probably did the most work, and the last person is the most senior 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 are indeed the definitions of or the statements of the meaning of the quality levels within the GRADE system for rating evidence that you are familiar with. A. I would have to compare it, but it looks approximately like what we used. In other words, even this is something that one might reword for your own purposes a little bit. Q. If you look at the definition of "Low," it says, quote, "Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect." Do you see that language? A. Yes. Q. And do you have an understanding of what that means, what it means if you assign that rating to the results of a study? A. So, yes. Q. What is that understanding? A. So I think this a lot of this is subjective ratings of evidence. And here, when you when the group decides something's of low

18 (Pages 66 - 69)

	Page 70		Page 72
1	you would say that your confidence in what's been	1	in terms of what we know and what's been found and
2	found, or the effect estimate, is not great, and	2	what's estimated to have been found, because even
3	that the true effect might be different from what is	3	statistics are just estimates.
4	being found, or not found, as the case may be.	4	So I think when you say the true effect is
5	Q. Just to pause for a moment. Am I correct	5	likely to be incredibly different from what is
6	that it is considered good practice, if you're	6	known, it's usually in a situation where we just
7	rating a body of evidence, to have more than one	7	don't have much of an estimate of effect or even any
8	rater independently evaluate each study?	8	estimate of effect; and therefore you don't really
9	A. We have, yeah.	9	know, and you actually not only don't you know,
10	Q. And then did you have a process for	10	but you don't have any confidence in what is
11	resolution if they disagreed?	11	being is out there.
12	A. Yes.	12	Q. So if you assigned a rating of very low to
13	Q. Was that documented in any way in what you	13	an individual published study in which a certain
14	disclosed to the public in connection with your	14	treatment is administered and a certain outcome is
15	NASPGHAN guidelines?	15	reported, am I correct that what you are saying with
16	A. I don't think it shows up in the final	16	that "very low" designation is, "The design of the
17	paper exactly. It's more well, actually, there	17	study is such that I have no confidence that, if it
18	are a couple of times that we couldn't come to	18	was repeated on a different patient, you would get
19	consensus, and we make that clear, that we have	19	the same outcome"?
20	certain things that we couldn't come to consensus	20	MS. LEVI: Object as to form.
21	on.	21	A. Yeah, well I'm actually not
22	And by the time you get to that point,	22	THE WITNESS: Can I answer? Or is that
23	you've gone through a lot of process here. This is	23	MS. LEVI: Yes.
24	around grading the various pieces of evidence that	24	A. I'm actually not sure that it would be
	Page 71		Page 73
1	are going into your recommendation.	1	about design of the study. It's just the bottom
2	But, yes, sometimes there was not enough to		line there is, you have a very low confidence in
3	•		
	even achieve consensus.	3	the well, this is about GRADE, but you have very
4		3	the well, this is about GRADE, but you have very low confidence in the known evidence that's out
	Q. The rating of "very low" states that the		low confidence in the known evidence that's out
4	Q. The rating of "very low" states that the articulation of what that means here in this paper	4 5	low confidence in the known evidence that's out there, and that if there was a different study or
45	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little	4 5 6	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also
4 5 6	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect	4 5 6	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this
4 5 6 7	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little	4 5 6	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like
4 5 6 7 8	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the	4 5 6 7 8	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of
4 5 6 7 8 9	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect."	4 5 6 7 8 9	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like
4 5 6 7 8 9 10	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is	4 5 6 7 8 9 10	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you
4 5 6 7 8 9 10 11	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating?	4 5 6 7 8 9 10 11	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people.
4 5 6 7 8 9 10 11 12	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right?	4 5 7 8 9 10 11 12 13	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough.
4 5 6 7 8 9 10 11 12 13	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have	4 5 7 8 9 10 11 12 13	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this
4 5 6 7 8 9 10 11 12 13 14	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the	4 5 6 7 8 9 10 11 12 13 14	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper.
4 5 6 7 8 9 10 11 12 13 14 15	 Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different 	4 5 6 7 8 9 10 11 12 13 14 15	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper. A. Okay.
4 5 6 7 8 9 10 11 12 13 14 15 16	Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different from what we have found so far.	4 5 6 7 8 9 10 11 12 13 14 15 16	 low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper. A. Okay. Q. Exhibit 6.
4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different from what we have found so far. Q. What does it mean to say that the true 	4 5 6 7 8 9 10 11 12 13 14 15 16 17	low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper. A. Okay. Q. Exhibit 6. A. Yes.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different from what we have found so far. Q. What does it mean to say that the true effect? I 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper. A. Okay. Q. Exhibit 6. A. Yes. Q. "GRADE guidelines: No. 3." And on the
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different from what we have found so far. Q. What does it mean to say that the true effect is different from the estimate of effect? I think, to a layman, that might be a bit cryptic. 	4 5 6 7 8 9 10 11 12 13 13 14 15 16 17 18 19	 low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper. A. Okay. Q. Exhibit 6. A. Yes. Q. "GRADE guidelines: No. 3." And on the first page in the second column is a Heading Number
$ \begin{array}{c} 4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\end{array} $	 Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different from what we have found so far. Q. What does it mean to say that the true effect is different from the estimate of effect? I think, to a layman, that might be a bit cryptic. What does that mean? 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper. A. Okay. Q. Exhibit 6. A. Yes. Q. "GRADE guidelines: No. 3." And on the first page in the second column is a Heading Number 2, "What we do not mean by quality of evidence,"
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different from what we have found so far. Q. What does it mean to say that the true effect? I think, to a layman, that might be a bit cryptic. What does that mean? A. So what it would mean again, and I'm 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper. A. Okay. Q. Exhibit 6. A. Yes. Q. "GRADE guidelines: No. 3." And on the first page in the second column is a Heading Number 2, "What we do not mean by quality of evidence," and then Heading 3 that says, "Opinion is not
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. The rating of "very low" states that the articulation of what that means here in this paper from Dr. Guyatt is, quote, "We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect." Do you have an understanding of what is meant by that definition of a very low rating? A. Again, for me, this is all relative, right? So "very low" is even less than "low." You have even less confidence in what's been found, and the true effect is likely to be incredibly different from what we have found so far. Q. What does it mean to say that the true effect is different from the estimate of effect? I think, to a layman, that might be a bit cryptic. What does that mean? A. So what it would mean again, and I'm sort of staying away from statistics, which affect 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 low confidence in the known evidence that's out there, and that if there was a different study or perhaps perhaps a different design, but it also could be that what I usually wind up in this world in is just a case study or something like that, that we don't actually know, based on an N of 1, what is going to happen if you did it across, you know, a thousand people. Q. Okay. Fair enough. Let me take you to the first page of this paper. A. Okay. Q. Exhibit 6. A. Yes. Q. "GRADE guidelines: No. 3." And on the first page in the second column is a Heading Number 2, "What we do not mean by quality of evidence," and then Heading 3 that says, "Opinion is not evidence."

19 (Pages 70 - 73)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 21 of 58

CONFIDENTIAL

		-	
	Page 74		Page 76
1	about 2005 this evidence-based medicine wasn't a	1	have to go on. Is that part of what you're telling
2	thing yet?	2	me?
3	A. Well, 1995.	3	A. No. I think they wrote a lot of paragraphs
4	Q. 1995, thank you.	4	here, because it is tricky in medicine to feel like
5	A. When I graduated from medical school, it	5	things are black and white. So, you know, they're
6	was just coming around.	6	just not that specific. You just can't be.
7	Q. I see the heading here that says, "Opinion	7	And so they're taking a lot of time here
8	is not evidence." And do you have an understanding	8	again, I'd have to get into it more to think
9	of what that means, what's being said in the context	9	about something I think all of us in guidelines
10	of evidence-based medicine?	10	think about, which is, okay, what do we how do we
11	A. Let me take a look at what they wrote here	11	take evidence, synthesize it, but also make sure
12	in this paragraph.	12	that we feel like we can have opinions on the body
13	Q. Please.	13	of the evidence we're looking at and can make a
14	A. (Reviewing document)	14	recommendation.
15	MS. LEVI: Take your time to review the	15	I mean, that is the consensus process
16	whole article if you need to as well.	16	around guidelines and the guideline development
17	Q. And, look, if the answer is, "I don't have	17	process in a nutshell. It's we have got evidence,
18	an opinion," that's fine. I just	18	but then we have to go beyond evidence, because
19	A. (Reviewing document)	19	evidence itself is not good enough, basically.
20	Q. Let me ask a better question.	20	Q. For purposes of guideline as the terms
21	A. Yeah, thanks.	21	are understood today in guideline development, do
22	Q. Let me withdraw that question, because I	22	you consider expert opinion itself to be scientific
23	don't want to just have you sit here and interpret	23	evidence?
24	what they wrote.	24	MS. LEVI: Object as to form.
	· · · · · · · · · · · · · · · · · · ·		
	D 75		D 77
1	Page 75	1	Page 77
1	A. Great.	1	A. So expert opinion, again, is I'm not
2	A. Great.Q. But that's context, and my question for you	2	A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who
23	A. Great.Q. But that's context, and my question for you now is, in your work today, for instance developing	2 3	A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an
2 3 4	A. Great.Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert	2 3 4	A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion?
2 3 4 5	A. Great.Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence?	2 3 4 5	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to
2 3 4	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. 	2 3 4	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a
2 3 4 5 6 7	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us 	2 3 4 5 6 7	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know,
2 3 4 5 6 7 8	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where 	2 3 4 5 6 7 8	A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I
2 3 4 5 6 7 8 9	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and 	2 3 4 5 6 7 8 9	A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly
2 3 4 5 6 7 8 9 10	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in 	2 3 4 5 6 7 8 9 10	A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of
2 3 4 5 6 7 8 9 10 11	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also 	2 3 4 5 6 7 8 9 10 11	A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance.
2 3 4 5 6 7 8 9 10 11 12	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence, then to also understand how strongly we were ready to make 	2 3 4 5 6 7 8 9 10 11 12	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's
2 3 4 5 6 7 8 9 10 11 12 13	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant 	2 3 4 5 6 7 8 9 10 11 12 13	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of
2 3 4 5 6 7 8 9 10 11 12 13 14	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. 	2 3 4 5 6 7 8 9 10 11 12 13 14	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these paragraphs here that I'm trying to read very quickly 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true? A. Experts are people who have emerged as
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these paragraphs here that I'm trying to read very quickly is this is very hard in medicine. It's very hard. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true? A. Experts are people who have emerged as giving statements and leading a field, but every
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these paragraphs here that I'm trying to read very quickly is this is very hard in medicine. It's very hard. You know, there is constantly a give-and-take on 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true? A. Experts are people who have emerged as giving statements and leading a field, but every expert does come with their own ways that they do
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these paragraphs here that I'm trying to read very quickly is this is very hard in medicine. It's very hard. You know, there is constantly a give-and-take on where is there evidence, what does that evidence 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true? A. Experts are people who have emerged as giving statements and leading a field, but every expert does come with their own ways that they do something.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these paragraphs here that I'm trying to read very quickly is this is very hard in medicine. It's very hard. You know, there is constantly a give-and-take on where is there evidence, what does that evidence mean, how does it apply to whatever you're trying to 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true? A. Experts are people who have emerged as giving statements and leading a field, but every expert does come with their own ways that they do something. And so, yes, you can see somebody as an
$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ \end{array}$	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these paragraphs here that I'm trying to read very quickly is this is very hard in medicine. It's very hard. You know, there is constantly a give-and-take on where is there evidence, what does that evidence mean, how does it apply to whatever you're trying to look at it for, and then where is there more 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true? A. Experts are people who have emerged as giving statements and leading a field, but every expert does come with their own ways that they do something. And so, yes, you can see somebody as an expert. You also want to understand how they how
$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ \end{array}$	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these paragraphs here that I'm trying to read very quickly is this is very hard in medicine. It's very hard. You know, there is constantly a give-and-take on where is there evidence, what does that evidence mean, how does it apply to whatever you're trying to look at it for, and then where is there more experience of it, experience driving opinion. So 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true? A. Experts are people who have emerged as giving statements and leading a field, but every expert does come with their own ways that they do something. And so, yes, you can see somebody as an expert. You also want to understand how they how they do it. So you sort of have to look beyond just
$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ \end{array}$	 A. Great. Q. But that's context, and my question for you now is, in your work today, for instance developing the NASPGHAN guidelines, did you consider expert opinion to be scientific evidence? MS. LEVI: Object as to form. A. Yeah, so I think it was incumbent upon us as a group to do our best to be understanding where there was evidence and what that evidence was and what the strength of the evidence was, and then, in the absence, especially, of evidence, then to also understand how strongly we were ready to make recommendations. And that was, like, a constant tension for us throughout the entire process. And I think why they're writing all these paragraphs here that I'm trying to read very quickly is this is very hard in medicine. It's very hard. You know, there is constantly a give-and-take on where is there evidence, what does that evidence mean, how does it apply to whatever you're trying to look at it for, and then where is there more experience of it, experience driving opinion. So Q. Well, so let me see if I understand what 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. So expert opinion, again, is I'm not sure what you mean by "expert opinion." Like, who makes somebody an expert, and how do they have an opinion? So I think it's just always trying to understand it and to be ready to see it as a relative thing, where you might have high, you know, medium, low, and even very low. It's like I mean, there's just basically it's constantly relativity to what we're doing in this process of trying to put it together and give people guidance. Q. Well, I'm not trying to be tricky. Let's assume that we're talking about the opinions of in your own field, I assume there are some people who everybody would acknowledge are experts, true? A. Experts are people who have emerged as giving statements and leading a field, but every expert does come with their own ways that they do something. And so, yes, you can see somebody as an expert. You also want to understand how they how

20 (Pages 74 - 77)

1	Page 78 Q. We talked earlier about evidence tables and	1	Page 80 Am I correct that a conditional
$\begin{vmatrix} 1\\2 \end{vmatrix}$	rating the strength of evidence. For purposes of		
	developing clinical practice guidelines, do you		recommendation, in some guidelines, the term that's
	consider expert opinion to be scientific evidence?	3	used for that is a "suggestion" or a "weak
4		4	recommendation"?
	A. No. I think it's important. So expert	5	A. Yeah
6	opinion becomes as important as whatever's been	6	MS. LEVI: Object as to form.
	published as evidence.	7	A. We had a very specific concept, which is "conditional recommendation" was defined as
8	Q. Okay. Let me take you back	8	
9	THE WITNESS: I have a bad question. Am I allowed to have a Coca-Cola?	9	suggesting that implementation might vary. So it
10		10	was recommended, but we knew that it might or might
11	MR. BROOKS: Absolutely.	11	not be something people would choose to implement.
12	THE WITNESS: Get some sugar.	12	Q. Did it also, whether it was a conditional
13	MS. LEVI: Just to be clear, at any time if	13	or unconditional recommendation, relate to any
14	you need a break, it's fair to ask for it.	14	extent to the strength of the evidence that you had
15	MR. BROOKS: Exactly.	15	to support that recommendation?
16	THE WITNESS: I left the coffee in the	16	A. So they were two different things that we
17	other room, and I think I need some sugar.	17	were, you know, grading. So we were grading the
18	MS. LEVI: If you want me to get your	18	quality of the evidence, and then we were also
19	coffee	19	making a recommendation. And very often our
20	THE WITNESS: No, no, no. It was quite	20	conditional recommendations were where there was low
21	cold.	21	quality evidence.
22	MS. LEVI: Nobody wants you to be	22	Q. And this is an example where you've
23	uncomfortable.	23	expressly said up front that there was low quality
24		24	evidence, right?
	Page 79		Page 81
1	BY MR. BROOKS:	1	A. Yes. This one had low quality evidence.
	() If you would find Lynhibit Logoin NAVD('LLAN		
2	Q. If you would find Exhibit 1 again, NASPGHAN		Q. And you also disclosed the vote in your
3	guideline I love that term.	3	consensus process?
34	guideline I love that term. A. Thank you. We've thought about a name	3 4	consensus process? A. Yes.
3 4 5	guideline I love that term.A. Thank you. We've thought about a name change, but it's hopeless at this point.	3 4 5	consensus process? A. Yes. Q. Which was a Delphi process?
34	guideline I love that term.A. Thank you. We've thought about a name change, but it's hopeless at this point.Q. And I'll be clear for the record, I'm using	3 4 5 6	consensus process?A. Yes.Q. Which was a Delphi process?A. We used a Delphi process to come to
3 4 5 6 7	guideline I love that term.A. Thank you. We've thought about a name change, but it's hopeless at this point.Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines	3 4 5 6 7	consensus process?A. Yes.Q. Which was a Delphi process?A. We used a Delphi process to come to consensus to vote on recommendations themselves.
3 4 5 6 7 8	guideline I love that term.A. Thank you. We've thought about a name change, but it's hopeless at this point.Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic	3 4 5 6 7 8	consensus process?A. Yes.Q. Which was a Delphi process?A. We used a Delphi process to come toconsensus to vote on recommendations themselves.Q. Is a Delphi process a fairly well defined
3 4 5 6 7 8 9	guideline I love that term.A. Thank you. We've thought about a name change, but it's hopeless at this point.Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this	3 4 5 6 7 8 9	consensus process?A. Yes.Q. Which was a Delphi process?A. We used a Delphi process to come toconsensus to vote on recommendations themselves.Q. Is a Delphi process a fairly well definedthing in the art?
3 4 5 6 7 8 9 10	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. 	3 4 5 6 7 8 9 10	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi,
3 4 5 6 7 8 9 10 11	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes 	3 4 5 6 7 8 9 10 11	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to
3 4 5 6 7 8 9 10 11 12	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper 	3 4 5 6 7 8 9 10 11 12	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do
3 4 5 6 7 8 9 10 11 12 13	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am	3 4 5 6 7 8 9 10 11 12 13	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get
3 4 5 6 7 8 9 10 11 12 13 14	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? 	3 4 5 6 7 8 9 10 11 12 13 14	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together.
3 4 5 6 7 8 9 10 11 12 13 14 15	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an
3 4 5 6 7 8 9 10 11 12 13 14 15 16	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have	3 4 5 6 7 8 9 10 11 12 13 14 15 16	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a few questions about. 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus. So Q. Is it a process is anonymity in the
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a few questions about. A. Okay.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus. So Q. Is it a process is anonymity in the voting an inherent part of the Delphi process?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a few questions about. A. Okay. Q. And this is Standard 36 is a conditional 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus. So Q. Is it a process is anonymity in the voting an inherent part of the Delphi process? A. Yes.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a few questions about. A. Okay. Q. And this is Standard 36 is a conditional recommendation that, quote, "Endoscopic biopsies 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the att? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus. So Q. Is it a process is anonymity in the voting an inherent part of the Delphi process? A. Yes. Q. Why is that?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a few questions about. A. Okay. Q. And this is Standard 36 is a conditional recommendation that, quote, "Endoscopic biopsies should be obtained as appropriate for the procedural 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus. So Q. Is it a process is anonymity in the voting an inherent part of the Delphi process? A. Yes. Q. Why is that? A. I think anonymity is a way of trying to
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a few questions about. A. Okay. Q. And this is Standard 36 is a conditional recommendation that, quote, "Endoscopic biopsies should be obtained as appropriate for the procedural indication, consistent with current evidence-based 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus. So Q. Is it a process is anonymity in the voting an inherent part of the Delphi process? A. Yes. Q. Why is that? A. I think anonymity is a way of trying to mitigate bias, to come back to that word. So
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 guideline I love that term. A. Thank you. We've thought about a name change, but it's hopeless at this point. Q. And I'll be clear for the record, I'm using this for exemplary purposes. These are guidelines relating to pediatric endoscopic procedures, a topic utterly unrelated to the subject matter of this case. And maybe that's a good thing. If you this paper, in fact, includes recommendations and suggestions this paper contains the guidelines that your team developed; am I right? A. Yes. Q. And if you would turn to Page 37, I have just picked an example, Standard 36, to ask you a few questions about. A. Okay. Q. And this is Standard 36 is a conditional recommendation that, quote, "Endoscopic biopsies should be obtained as appropriate for the procedural 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 consensus process? A. Yes. Q. Which was a Delphi process? A. We used a Delphi process to come to consensus to vote on recommendations themselves. Q. Is a Delphi process a fairly well defined thing in the art? A. So most of us talk about a modified Delphi, because Delphi itself was probably way prior to where we are now, which is lots of ways you can do things across continents without having to get together. But Delphi is well described, and it's an iterative, good process for coming to consensus. So Q. Is it a process is anonymity in the voting an inherent part of the Delphi process? A. Yes. Q. Why is that? A. I think anonymity is a way of trying to

21 (Pages 78 - 81)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 23 of 58

CONFIDENTIAL

	Page 82		Page 84
1	anonymous?	1	conditional?
2	A. I think that the Delphi process is designed	2	A. Well, I think there's a debate about
3	to let each individual stand, you know, in their own	3	frankly what is that. So pediatric endoscopy is a
4	convictions and their own you know, to basically	4	field where we take longer with colonoscopies for
5	vote on their own decisions on how they want to do	5	lots of different reasons, and I don't think we have
6	things.	6	tended to be focused on time the way that adult
7	And, yeah, it's just important, because it	7	colonoscopists have.
8	doesn't let necessarily one person sway a process,	8	And so there's actually a lot of people who
9	like what would happen in an open room. So	9	are reticent. I'll tell you, I personally voted
10	Q. You might have somebody who is highly	10	"strongly agree" there. I agree with you, for me
11	respected that more junior participants are	11	this was a no-brainer. But there are a lot of
12	reluctant to disagree with?	12	people who are quite reticent to have there be some
13	A. Sure. That could happen.	13	sort of regulation or, in this case, a standard,
14	Q. You might have peer pressure of some sort,	14	even, to say, you know, that time matters.
15	that somebody is reluctant to be the odd man out?	15	So that's still a foreign concept in
16	A. Yeah.	16	pediatric GI. And it turned out we didn't have much
17	Q. Has every Delphi process that you've ever	17	evidence to say that it needs to happen in an
18	participated in been anonymous in its voting?	18	efficient way.
19	A. Yes.	19	Q. So in the evidence was low quality even
20	Q. Why did you disclose the breakout of the	20	if it seemed common sense, if the evidence is low
21	vote?	21	quality, you would generally give only a conditional
22	A. We made a decision early on, before we did	22	recommendation?
23	any of it again, working with methodologists and	23	MS. LEVI: Object as to form.
24	trying to decide how we were proceeding with what	24	A. Yeah, no, there are really two different
	Page 83		Page 85
1	we were going to do. So that was all decided a	1	things. And so you sort of got to this, and then it
2	priori.	2	was like, "All right, are we ready to vote on this
3	Q. If you back up to Page 36, Standard 32.	3	recommendation?"
4	A. Yes.	4	So, again, the conditional recommendation
5	Q. This standard says, "Pediatric endoscopic		
		5	is saying that we're going to recommend it, but we
6	procedures should be performed efficiently, within a	6	appreciate that implementing it may be not something
7	reasonable procedure time."	5 6 7	appreciate that implementing it may be not something you have to do; versus a strong recommendation was,
7 8	reasonable procedure time." I take it, in layman's terms, that means	6 7 8	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is
7 8 9	reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding,	6 7 8 9	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective.
7 8 9 10	reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us?	6 7 8 9 10	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that
7 8 9 10 11	reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah.	6 7 8 9 10 11	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily
7 8 9 10 11 12	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional 	6 7 8 9 10 11 12	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But,
7 8 9 10 11 12 13	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low 	6 7 8 9 10 11 12 13	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we
7 8 9 10 11 12 13 14	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? 	6 7 8 9 10 11 12 13 14	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was
7 8 9 10 11 12 13 14 15	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. 	6 7 8 9 10 11 12 13 14 15	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and
7 8 9 10 11 12 13 14 15 16	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. Q. And indeed, the recommendation, only 37.5 	6 7 8 9 10 11 12 13 14 15 16	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level.
7 8 9 10 11 12 13 14 15 16 17	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. Q. And indeed, the recommendation, only 37.5 percent of the participants strongly agreed with it; 	6 7 8 9 10 11 12 13 14 15 16 17	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level. Q. Let me just put a caution out on the table.
7 8 9 10 11 12 13 14 15 16 17 18	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. Q. And indeed, the recommendation, only 37.5 percent of the participants strongly agreed with it; am I right in understanding this correctly? 	6 7 8 9 10 11 12 13 14 15 16 17 18	 appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level. Q. Let me just put a caution out on the table. We do this all the time in ordinary speech. You
7 8 9 10 11 12 13 14 15 16 17 18 19	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. Q. And indeed, the recommendation, only 37.5 percent of the participants strongly agreed with it; am I right in understanding this correctly? A. Yes. 	6 7 8 9 10 11 12 13 14 15 16 17 18 19	appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level. Q. Let me just put a caution out on the table. We do this all the time in ordinary speech. You began that answer, "Yeah, no."
7 8 9 10 11 12 13 14 15 16 17 18 19 20	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. Q. And indeed, the recommendation, only 37.5 percent of the participants strongly agreed with it; am I right in understanding this correctly? A. Yes. Q. Now, the recommendation that you perform 	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level. Q. Let me just put a caution out on the table. We do this all the time in ordinary speech. You began that answer, "Yeah, no." A. Oh.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. Q. And indeed, the recommendation, only 37.5 percent of the participants strongly agreed with it; am I right in understanding this correctly? A. Yes. Q. Now, the recommendation that you perform these procedures efficiently within a reasonable 	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level. Q. Let me just put a caution out on the table. We do this all the time in ordinary speech. You began that answer, "Yeah, no." A. Oh. Q. And in a deposition, that doesn't work
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. Q. And indeed, the recommendation, only 37.5 percent of the participants strongly agreed with it; am I right in understanding this correctly? A. Yes. Q. Now, the recommendation that you perform these procedures efficiently within a reasonable time off the cuff seems, to use a technical term, a 	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level. Q. Let me just put a caution out on the table. We do this all the time in ordinary speech. You began that answer, "Yeah, no." A. Oh. Q. And in a deposition, that doesn't work terribly well.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 reasonable procedure time." I take it, in layman's terms, that means don't dawdle in your procedure. Am I understanding, more or less, what it's telling us? A. Yeah. Q. And this also is a conditional recommendation, and it states that there's very low quality evidence, correct? A. Yes. Q. And indeed, the recommendation, only 37.5 percent of the participants strongly agreed with it; am I right in understanding this correctly? A. Yes. Q. Now, the recommendation that you perform these procedures efficiently within a reasonable 	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 appreciate that implementing it may be not something you have to do; versus a strong recommendation was, we actually think you need to do this, like, this is from a safety and quality perspective. So then the voting, you're just seeing that it really and it really wasn't necessarily everyone ready to say that time was important. But, again, a priori we had said, "Well, what are we going to say is a recommendation?" And it was actually you had to combine the "strongly agree" and "agree" and be, you know, on a certain level. Q. Let me just put a caution out on the table. We do this all the time in ordinary speech. You began that answer, "Yeah, no." A. Oh. Q. And in a deposition, that doesn't work

22 (Pages 82 - 85)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 24 of 58

CONFIDENTIAL

	Page 86		Page 88
1	A. Yeah.	1	not for the procedure itself?
2	Q. It's just sort of a thing. So let me	2	A. Right.
3	I'll just ask you a new question. It doesn't really	3	Q. And, again, in this set of guidelines, your
4	matter. I'll just caution you.	4	team used GRADE to rate the strength of the
5	A. Okay.	5	supporting evidence; am I right?
6	Q. Am I correct that, most commonly, if all	6	Not a memory test. I think it says so at
7	you have is weak evidence for a recommendation, you	7	the bottom of the first column on the first page.
8	would expect that recommendation to be a conditional	8	A. I don't actually remember that we used
9	or a weak a conditional recommendation or a	9	GRADE.
10	suggestion?	10	Q. Well, again, I'm not testing your first
11	MS. LEVI: Object as to form.	11	page, first column, at the bottom of the
12	A. I mean, I think we we would say it's	12	MS. LEVI: You can take your time to
13	hard to make like, to have strong evidence and	13	read
14	then have a conditional recommendation. And I think	14	THE WITNESS: Yeah, let me
15	it's probably I mean, again, the low quality	15	MS. LEVI: and review your own article.
16	evidence is not going to make it possible to have a	16	That's okay.
17	strong recommendation, usually.	17	THE WITNESS: Yeah, no, this is part of the
18	Q. I can't promise we won't come back to that	18	evolution.
19	again. I just love it so much.	19	A. (Reviewing document) We used yeah. We
20	MR. BROOKS: Let me ask the reporter to	20	used GRADE criteria at the very end to talk about
21	mark as Exhibit 7 a paper from 2018, the lead author	21	the recommendations, but we didn't use GRADE
22	Dayna Early, a number of authors including Dr.	22	methodology. This is this was the state of the
23	Lightdale, entitled "Guidelines for sedation and	23	art from, like, I don't know, 2010 to again, this
24	anesthesia in GI endoscopy."	24	came out in 2018. We were probably working on this
1	Page 87	1	Page 89
	(Document marked as Lightdale	1	one in 2016, you know.
	Exhibit 7 for identification)	2	So we were using GRADE criteria
2	Exhibit 7 for identification)	2	So we were using GRADE criteria actually yes, published August 2017 is when we
23	Q. And, Dr. Lightdale, my first question is,	3	actually, yes, published August 2017 is when we
2 3 4	Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the	3 4	actually, yes, published August 2017 is when we started looking at things.
2 3 4 5	Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record.	3 4 5	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE
2 3 4 5 6	Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record.A. Yes.	3 4 5 6	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process.
2 3 4 5 6 7	Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record.A. Yes.Q. What is this?	3 4 5	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of
2 3 4 5 6 7 8	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for 	3 4 5 6 7 8	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract,"
2 3 4 5 6 7	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was 	3 4 5 6	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of
2 3 4 5 6 7 8 9	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards 	3 4 5 6 7 8 9	 actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah.
2 3 4 5 6 7 8 9 10	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was 	3 4 5 6 7 8 9 10	 actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it?
2 3 4 5 6 7 8 9 10 11	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of 	3 4 5 6 7 8 9 10 11	 actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is
2 3 4 5 6 7 8 9 10 11 12	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. 	3 4 5 6 7 8 9 10 11 12	 actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based
2 3 4 5 6 7 8 9 10 11 12 13	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you 	3 4 5 6 7 8 9 10 11 12 13	 actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength
2 3 4 5 6 7 8 9 10 11 12 13 14	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. 	3 4 5 6 7 8 9 10 11 12 13 14	 actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. A. Yes. 	3 4 5 6 7 8 9 10 11 12 13 14 15	 actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)."
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. A. Yes. Q. "Second author" implies that you were 	3 4 5 6 7 8 9 10 11 12 13 14 15 16	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)." And if we turn to Table 1, that is headed
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. A. Yes. Q. "Second author" implies that you were substantially involved, more than many of those 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)." And if we turn to Table 1, that is headed "System for rating the quality of evidence for
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. A. Yes. Q. "Second author" implies that you were substantially involved, more than many of those authors? 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)." And if we turn to Table 1, that is headed "System for rating the quality of evidence for guidelines." It's footnoted, "Adapted from Guyatt
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. A. Yes. Q. "Second author" implies that you were substantially involved, more than many of those authors? A. I was substantially involved. 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)." And if we turn to Table 1, that is headed "System for rating the quality of evidence for guidelines." It's footnoted, "Adapted from Guyatt et al." And it has definitions which I we could
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. A. Yes. Q. "Second author" implies that you were substantially involved, more than many of those authors? A. I was substantially involved. Q. All right. And this is a different set of 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)." And if we turn to Table 1, that is headed "System for rating the quality of evidence for guidelines." It's footnoted, "Adapted from Guyatt et al." And it has definitions which I we could take the time it matches the list of previous
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ \end{array} $	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. A. Yes. Q. "Second author" implies that you were substantially involved, more than many of those authors? A. I was substantially involved. Q. All right. And this is a different set of guidelines being created by a different team; am I 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)." And if we turn to Table 1, that is headed "System for rating the quality of evidence for guidelines." It's footnoted, "Adapted from Guyatt et al." And it has definitions which I we could take the time it matches the list of previous definitions in the table that we looked at earlier.
$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ \end{array}$	 Q. And, Dr. Lightdale, my first question is, can you identify this document, this paper for the record. A. Yes. Q. What is this? A. So this was what we called a guideline for sedation and anesthesia in GI endoscopy that I was the second author on that came out of the Standards of Practice Committee for the American Society of Gastrointestinal Endoscopy. Q. And "second author" implies that you there's a lot of names there. A. Yes. Q. "Second author" implies that you were substantially involved, more than many of those authors? A. I was substantially involved. Q. All right. And this is a different set of guidelines being created by a different team; am I correct? 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	actually, yes, published August 2017 is when we started looking at things. But we didn't actually use the GRADE process. Q. Well, let me ask this: The last line of the first column I was going to say "abstract," but it's not exactly an abstract, is it? A. Yeah. Q. Whatever it is, the first column, which is in italics, reads, "The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence by using the GRADE criteria (Table 1)." And if we turn to Table 1, that is headed "System for rating the quality of evidence for guidelines." It's footnoted, "Adapted from Guyatt et al." And it has definitions which I we could take the time it matches the list of previous definitions in the table that we looked at earlier. MS. LEVI: I'm going to ask, if you're

23 (Pages 86 - 89)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 25 of 58

CONFIDENTIAL

1	Page 90		Page 92
1	MR. BROOKS: That's a representation.		related to sedation and anesthesia, they're not
2	MS. LEVI: that you are familiar	2	antique. 2018 is not that many years ago.
3	Q. We can go back to my favorite document,	3	A. Correct.
4	which is to say Exhibit 1 no, it's not.	4	Q. Why did your team not use a GRADE system
5	Lightdale Exhibit 6 contains, on Page 404, the	5	for rating the evidence in the course of developing
6	definitions.	6	those guidelines?
	MS. LEVI: Take the time you need to	7	A. So in 2017 again, my memory is probably
	respond accurately to the question that may be asked.	8	in 2016 I got assigned this with Dayna in the
			Standards of Practice Committee that I was sitting on. And we basically we were just, as a society
10	Q. And my only point and there is no	10	
11	question at the moment my only point is that the	11	and as a group, and I would argue across most of
12	list of definitions contained in your paper from	12 13	medicine, people were really not yet ready to put in the tremendous effort it takes to do the GRADE
13	2018 seems to correspond to the column labeled "Previous definition" on Page 404 of Lightdale		
14	Exhibit 6.	14 15	process.
			And so it's being discussed by experts out
16	And if you'd like to check that, that's fine.	16	there and mentioned, and people are hearing the
	A. Yes. It does.	17	term, but what it actually means to do it is a lot of work. And that is not where we were at ASGE in,
18 19	Q. All right. And in the right-hand column in	18	you know, 2016, 2017, as we were doing this thing,
20	your 2018 paper is it says "Symbol," and it shows	19 20	and it ultimately comes out in 2018.
$\begin{vmatrix} 20\\21 \end{vmatrix}$	little circles with crosses.	20	MR. BROOKS: Okay. Let me ask the reporter
$\begin{vmatrix} 21\\22 \end{vmatrix}$	Are those symbols widely used and	21	to mark as Exhibit 8 one of the GRADE Series papers,
22	recognized in connection with GRADE ratings?	22	No. 14, quote, "Going from evidence to
23	A. Not necessarily. So without a doubt		recommendations: the significance and presentation
24	A. Not necessarily. So without a doubt	24	recommendations, the significance and presentation
1	Page 91	1	Page 93
1	it's funny, I have strong memories of this paper.	1	of recommendations."
2	it's funny, I have strong memories of this paper. We were not using the GRADE process, but	2	of recommendations." (Document marked as Lightdale
23	it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was	2 3	of recommendations." (Document marked as Lightdale Exhibit 8 for identification)
2 3 4	it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria,	2 3 4	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think
2 3 4 5	it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again,	2 3 4 5	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today?
2 3 4 5 6	it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right?	2 3 4 5 6	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No.
2 3 4 5 6 7	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. 	2 3 4 5 6 7	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you
2 3 4 5 6 7 8	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at 	2 3 4 5 6 7 8	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than
2 3 4 5 6 7 8 9	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. 	2 3 4 5 6 7 8 9	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors.
2 3 4 5 6 7 8 9 10	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the 	2 3 4 5 6 7 8 9 10	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720
2 3 4 5 6 7 8 9 10 11	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we 	2 3 4 5 6 7 8 9 10 11	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract
2 3 4 5 6 7 8 9 10 11 12	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" 	2 3 4 5 6 7 8 9 10 11 12	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is
2 3 4 5 6 7 8 9 10 11 12 13	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There 	2 3 4 5 6 7 8 9 10 11 12 13	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark.
2 3 4 5 6 7 8 9 10 11 12 13 14	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a 	2 3 4 5 6 7 8 9 10 11 12 13 14	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the rigor. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text line reads, "If the panel is highly confident of the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the rigor. Q. Would you spell that for the reporter, 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text line reads, "If the panel is highly confident of the balance between desirable and undesirable
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the rigor. Q. Would you spell that for the reporter, PEnQuIN. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text line reads, "If the panel is highly confident of the balance between desirable and undesirable consequences, they make a strong recommendation
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the rigor. Q. Would you spell that for the reporter, PEnQuIN. A. Sure. P-E-n-Q-u-I-N, which is the 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text line reads, "If the panel is highly confident of the balance between desirable and undesirable consequences, they make a strong recommendation for or against an intervention."
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the rigor. Q. Would you spell that for the reporter, PEnQuIN. A. Sure. P-E-n-Q-u-I-N, which is the Pediatric Endoscopic Quality Improvement Network. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text line reads, "If the panel is highly confident of the balance between desirable and undesirable consequences, they make a strong recommendation for or against an intervention." Do you see that?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the rigor. Q. Would you spell that for the reporter, PEnQuIN. A. Sure. P-E-n-Q-u-I-N, which is the Pediatric Endoscopic Quality Improvement Network. Q. Otherwise we're going get a transcript that 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text line reads, "If the panel is highly confident of the balance between desirable and undesirable consequences, they make a strong recommendation for or against an intervention." Do you see that? A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 it's funny, I have strong memories of this paper. We were not using the GRADE process, but what we did at the end, and this is what ASGE was doing at the time, is we used this GRADE criteria, this previous definition of GRADE again, everything has been an evolution, right? Q. Right. A. But this previous definition, we looked at that as we looked at our recommendations. In other words, we came up with the recommendations and then we said, "Okay, how do we feel?" And this was not a Delphi process. There was a lot to this that is really, frankly, just at a different level than where we are now, like where my PEnQuIN document is, let's say, in terms of the rigor. Q. Would you spell that for the reporter, PEnQuIN. A. Sure. P-E-n-Q-u-I-N, which is the Pediatric Endoscopic Quality Improvement Network. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	of recommendations." (Document marked as Lightdale Exhibit 8 for identification) Q. And, again, Dr. Lightdale, do you think that you've seen this paper before today? A. No. Q. Then I will ask you I mean to ask you about your practices and understanding rather than to interpret the meaning of the authors. So let me ask you to turn to Page 720 and actually, why don't you read the abstract just for context so you know what that paper is about and we're not working in the dark. A. (Reviewing document) Okay. Q. Now let me ask you to turn to Page 720. And the second column, beginning in the third text line reads, "If the panel is highly confident of the balance between desirable and undesirable consequences, they make a strong recommendation for or against an intervention." Do you see that?

24 (Pages 90 - 93)

1	Page 94	1	Page 96
	you have gone about deciding what merits or does not	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	pushing us. In fact, the abstract that you asked me
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	merit a strong recommendation?	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	to read says this. Don't shy away from not (sic)
3	A. I mean, yes and no.		making a recommendation. It's important to make
4	Q. Okay.	4	recommendations, because if you don't make a
5	A. So I think I have not sat in a panel and	5	recommendation, you still leave people in the dark.
6	thought about this, you know, desirable,	6	So it is a grappling process to try to
7	undesirable. We haven't sat there and weighed that	7	figure out, okay, how do we make the recommendation
8	kind of stuff.	8	Q. In that process, do you, as a physician
9	But I would say, instinctively and	9	well, let's take it in a clinical process system
10	inherently, to make a strong recommendation, you	10	first.
11	have brought into play discussions around desirable	11	Do you, as a physician, deciding on
12	and undesirable consequences.	12	treatment for a patient, have an obligation to
13	So people are thinking about that, and that	13	consider both long- and short-term consequences of
14	could be either desirable health outcomes, or I	14	administering the treatment or withholding the
15	think there's a lot of, I would call it, risk/	15	treatment?
16	benefit weighing that's going on with	16	MS. LEVI: Object as to form.
17	recommendations and what are the risks to making a	17	A. I would say not always, is the truth.
18	strong recommendation for or a strong recommendation	18	Q. In what context, if any, would you have no
19	against something, what's the risk of that.	19	obligation to consider the long-term consequences?
20	So strong recommendations are to be done	20	A. When there's life or death on the line.
21	very carefully.	21	Q. Okay. And have you yourself faced those
22	Q. Well, the next sentence reads, quote, "If	22	situations?
23	the panel has less confidence of the balance between	23	A. Yeah.
24	desirable and undesirable consequences, they offer a	24	Q. And what degree of threat or imminence of
	Page 95		Page 97
1	weak recommendation."	1	death, to your understanding, makes it appropriate
2	Do you see that?	2	for you as a physician to put aside considerations
3	A. Yes.	3	of long-term impacts?
4	Q. And is that relating to what you just	4	A. So I'm in pediatric GI, so we certainly
5	explained to me?	5	encounter situations where, if we do not act within
6	A. Yeah. I think, again, in practice that	6	the next 15 minutes, somebody will die, and you
7	kind of happens.	7	actually do need to do something.
8	Q. So you need to be fairly confident that you	8	So, you know, not at that moment, I'm
9	understand let me start again.	9	not worrying about the long term. I'm worrying
10	You need to have a fairly confident	10	about what needs to be solved at that moment to get
11	evaluation of the upside of the treatment in	11	the patient out of the situation.
12	question and also a fairly confident understanding	12	Q. Absent an imminent threat of death, do you
1 * 4		1	-
13	of the risks or downside before you can offer a	13	believe that you, as a physician, have an obligation
	of the risks or downside before you can offer a	13 14	
13			believe that you, as a physician, have an obligation to consider both long-term and short-term consequences of a potential treatment as you make
13 14	of the risks or downside before you can offer a strong recommendation; am I correct? MS. LEVI: Object as to form.	14	to consider both long-term and short-term
13 14 15	of the risks or downside before you can offer a strong recommendation; am I correct?	14 15	to consider both long-term and short-term consequences of a potential treatment as you make decisions for or with a patient?
13 14 15 16	of the risks or downside before you can offer a strong recommendation; am I correct? MS. LEVI: Object as to form. A. I guess I'm not sure if you're restating what I tried to state.	14 15 16	to consider both long-term and short-term consequences of a potential treatment as you make decisions for or with a patient? A. I'm in pediatrics, so long-term discussions
13 14 15 16 17 18	of the risks or downside before you can offer a strong recommendation; am I correct? MS. LEVI: Object as to form. A. I guess I'm not sure if you're restating what I tried to state. But I think a panel ultimately is	14 15 16 17 18	to consider both long-term and short-termconsequences of a potential treatment as you makedecisions for or with a patient?A. I'm in pediatrics, so long-term discussionsof things is really tricky. You know, what are we
13 14 15 16 17 18 19	of the risks or downside before you can offer a strong recommendation; am I correct? MS. LEVI: Object as to form. A. I guess I'm not sure if you're restating what I tried to state. But I think a panel ultimately is everybody in that panel is, in their head, weighing	14 15 16 17 18 19	to consider both long-term and short-termconsequences of a potential treatment as you makedecisions for or with a patient?A. I'm in pediatrics, so long-term discussionsof things is really tricky. You know, what are wetalking? Five years out? Ten years out? Fifty
13 14 15 16 17 18 19 20	of the risks or downside before you can offer a strong recommendation; am I correct? MS. LEVI: Object as to form. A. I guess I'm not sure if you're restating what I tried to state. But I think a panel ultimately is everybody in that panel is, in their head, weighing what's good about making that recommendation and	14 15 16 17 18 19 20	to consider both long-term and short-termconsequences of a potential treatment as you makedecisions for or with a patient?A. I'm in pediatrics, so long-term discussionsof things is really tricky. You know, what are wetalking? Five years out? Ten years out? Fiftyyears out? You know, that's no, I think we can't
13 14 15 16 17 18 19 20 21	of the risks or downside before you can offer a strong recommendation; am I correct? MS. LEVI: Object as to form. A. I guess I'm not sure if you're restating what I tried to state. But I think a panel ultimately is everybody in that panel is, in their head, weighing what's good about making that recommendation and what could be a downside or undesirable or a risk of	14 15 16 17 18 19 20 21	to consider both long-term and short-term consequences of a potential treatment as you make decisions for or with a patient? A. I'm in pediatrics, so long-term discussions of things is really tricky. You know, what are we talking? Five years out? Ten years out? Fifty years out? You know, that's no, I think we can't always be fully sure of the long-term stuff, because
13 14 15 16 17 18 19 20 21 22	of the risks or downside before you can offer a strong recommendation; am I correct? MS. LEVI: Object as to form. A. I guess I'm not sure if you're restating what I tried to state. But I think a panel ultimately is everybody in that panel is, in their head, weighing what's good about making that recommendation and what could be a downside or undesirable or a risk of making a recommendation, or not making a	14 15 16 17 18 19 20 21 22	to consider both long-term and short-term consequences of a potential treatment as you make decisions for or with a patient? A. I'm in pediatrics, so long-term discussions of things is really tricky. You know, what are we talking? Five years out? Ten years out? Fifty years out? You know, that's no, I think we can't always be fully sure of the long-term stuff, because long term can be a very long time in pediatrics.
13 14 15 16 17 18 19 20 21	of the risks or downside before you can offer a strong recommendation; am I correct? MS. LEVI: Object as to form. A. I guess I'm not sure if you're restating what I tried to state. But I think a panel ultimately is everybody in that panel is, in their head, weighing what's good about making that recommendation and what could be a downside or undesirable or a risk of	14 15 16 17 18 19 20 21	to consider both long-term and short-term consequences of a potential treatment as you make decisions for or with a patient? A. I'm in pediatrics, so long-term discussions of things is really tricky. You know, what are we talking? Five years out? Ten years out? Fifty years out? You know, that's no, I think we can't always be fully sure of the long-term stuff, because

25 (Pages 94 - 97)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 27 of 58

CONFIDENTIAL

Page 98		Page 100
-	1	Q. Okay.
	2	721, Column 2.
A. Sure.	3	A. Okay.
Q. Give me an example.	4	Q. At the bottom is a section headed "Meaning
	5	of recommendations in GRADE." We've talked earlier
	6	about evaluating the strength of evidence, and now
the line.	7	we're talking about the GRADE labels for
Q. So is that a context in which you do or you	8	recommendations.
	9	And the first sentence in that section
	10	reads, "Using the GRADE approach, guideline authors
-		make a strong recommendation when they believe that
		all or almost all informed people would make the
		recommendation choice for or against an
		intervention."
	15	Let me ask whether that understanding of a
		strong recommendation is consistent with how you and
		your colleagues have worked, for instance, in
		creating the NASPGHAN guideline.
		A. I don't know that we have used that exact
		framework for talking about when to use a "strong
		recommendation." So I hadn't read this before, and
	22	I don't remember that that was what we said.
	23	MR. BROOKS: Okay. Let me ask the reporter
Q. Go for it. Think.	24	to mark as Exhibit 9 GRADE Guidelines Paper Number
Page 99		Page 101
-	1	15, "Going from evidence to recommendation -
	2	determinants of a recommendation's direction and
-	3	strength."
	4	(Document marked as Lightdale
•	5	Exhibit 9 for identification)
	6	Q. And, Dr. Lightdale, I assume, but correct
So there can be a discussion of, do we	7	me if I'm wrong, you have not seen this particular
really need to do the endoscopy? And the answer is,	8	paper before today?
well, if you this is my thinking; I'm not an	9	A. I have not. Shall I read the abstract?
ethicist, but I explain that I think there is an	10	Q. I'm going to take you you certainly may
ethical question on the line which is, right now,	11	read the abstract, or you can listen to my question
while the disease is not yet treated, if I do the	12	and then decide whether you want to read the
-	12	abstract.
endoscopy, we will have evidence of the disease.	15	
endoscopy, we will have evidence of the disease. And in 20 years, after 20 years of treating the	13	A. Okay. Go ahead.
		A. Okay. Go ahead.Q. If you turn to Page 731, there is, on the
And in 20 years, after 20 years of treating the	14	Q. If you turn to Page 731, there is, on the
And in 20 years, after 20 years of treating the disease, and now the child is an adult and they say,	14 15	Q. If you turn to Page 731, there is, on the
And in 20 years, after 20 years of treating the disease, and now the child is an adult and they say, you know, "I'm not sure I ever had celiac disease.	14 15 16	Q. If you turn to Page 731, there is, on the first column, a heading "Confidence in estimates of
And in 20 years, after 20 years of treating the disease, and now the child is an adult and they say, you know, "I'm not sure I ever had celiac disease. Maybe I don't need to be doing what I'm doing," that	14 15 16 17	Q. If you turn to Page 731, there is, on the first column, a heading "Confidence in estimates of effect (quality of evidence)." Do you see that?
And in 20 years, after 20 years of treating the disease, and now the child is an adult and they say, you know, "I'm not sure I ever had celiac disease. Maybe I don't need to be doing what I'm doing," that is a long-term potential complication that could	14 15 16 17 18	Q. If you turn to Page 731, there is, on the first column, a heading "Confidence in estimates of effect (quality of evidence)." Do you see that?A. Yes.
And in 20 years, after 20 years of treating the disease, and now the child is an adult and they say, you know, "I'm not sure I ever had celiac disease. Maybe I don't need to be doing what I'm doing," that is a long-term potential complication that could come up.	14 15 16 17 18 19	Q. If you turn to Page 731, there is, on the first column, a heading "Confidence in estimates of effect (quality of evidence)." Do you see that?A. Yes.Q. And if you go down, the third paragraph
And in 20 years, after 20 years of treating the disease, and now the child is an adult and they say, you know, "I'm not sure I ever had celiac disease. Maybe I don't need to be doing what I'm doing," that is a long-term potential complication that could come up. So I say, "We better do the endoscopy, even	14 15 16 17 18 19 20	 Q. If you turn to Page 731, there is, on the first column, a heading "Confidence in estimates of effect (quality of evidence)." Do you see that? A. Yes. Q. And if you go down, the third paragraph below there begins, "For instance." Do you see
And in 20 years, after 20 years of treating the disease, and now the child is an adult and they say, you know, "I'm not sure I ever had celiac disease. Maybe I don't need to be doing what I'm doing," that is a long-term potential complication that could come up. So I say, "We better do the endoscopy, even though it has risks right now, because in 20 years,	14 15 16 17 18 19 20 21	Q. If you turn to Page 731, there is, on the first column, a heading "Confidence in estimates of effect (quality of evidence)." Do you see that?A. Yes.Q. And if you go down, the third paragraph below there begins, "For instance." Do you see that?
	 Q. Give me an example. A. We use biologics to treat inflammatory bowel disease, and they can have cancer risks down the line. Q. So is that a context in which you do or you don't consider the long-term risk as you talk with parents? A. I put it out there that there are potential long-term risks. But then I weigh it against other long-term risks, including not treating the disease with the biologics, which still holds a cancer risk. And there's almost no ways to really weigh these things. But people try to imagine long term, and, you know, I do my best to help them think about it. I think about it, et cetera. Q. Is there other any other example that comes to mind of decisions you participate in that have potential lifelong implications? A. Sure. I'm going to have to think now. That one came quickly. Q. Go for it. Think. Page 99 A. Yes. I'll give you one. So in the diagnosis of celiac disease, there's a movement not to do endoscopy and get the biopsies that we read about in our standards, because that incurs risk to do that, especially in a young child. So there can be a discussion of, do we really need to do the endoscopy? And the answer is, well, if you this is my thinking; I'm not an ethicist, but I explain that I think there is an ethical question on the line which is, right now, while the disease is not yet treated, if I do the 	you, as a doctor, participate in deciding have potential lifelong downside risks?1potential lifelong downside risks?2A. Sure.3Q. Give me an example.4A. We use biologics to treat inflammatory5bowel disease, and they can have cancer risks down the line.7Q. So is that a context in which you do or you don't consider the long-term risk as you talk with parents?9Dom-term risks. But ther I weigh it against other long-term risks. But then I weigh it against other long-term risks. Including not treating the disease with the biologics, which still holds a cancer risk.14And there's almost no ways to really weigh these things. But people try to imagine long term, and, you know, I do my best to help them think about it. I think about it, et cetera.18Q. Is there other any other example that comes to mind of decisions you participate in that have potential lifelong implications?21A. Sure. I'm going to have to think now.22That one came quickly. Q. Go for it. Think.24Page 997A. Yes. I'll give you one. So in the diagnosis of celiac disease, there's a movement not to do endoscopy and get the biopsies that we read about in our standards, because that incurs risk to do that, especially in a young child.6So there can be a discussion of, do we really need to do the endoscopy? And the answer is, well, if you this is my thinking; I'm not an ethicial question on the line which is, right now, while the disease is not yet treated, if I do the10

26 (Pages 98 - 101)

1"For instance, the GRADE approach provides2insight into how guideline panels should have3handled the decision regarding hormone replacement4therapy (HRT) in postmenopausal women in the 1990s5when observational studies suggested a substantial6reduction in cardiovascular risk (which randomized7trials subsequently proved false, at least in women8appreciably past menopause), and equally low9evidence quality suggested an increase in the risk10of breast cancer (which proved true)," close quote.11Really my opening question is, do you have12some familiarity with the narrative in the medical13field of a period of time in which doctors and14indeed guidelines were recommending post-menopause15hormone therapy for women, and subsequently those16recommendations were changed?17A. No.18Q. Okay. That's not a case study that19A. No.20Q you've been through in either school or21in any sort of conference?22A. I went to pediatrics, and so by, you know,231995 I was really in pediatrics and frankly not yet24myself in menopause. So					
2 insight into how guideline panels should have 2 12-point plan was written by Dr. Coleman, Eli 3 handled the decision regarding hormone replacement 3 Coleman, Is that a name that means anything to you? 4 therapy (IRT) in postmenopausal women in the 1990s. 5 when observational studies suggested a substantial 6 reduction in cardiovascular risk (which randomized A. No. 5 Q. I will also represent to you that he was 6 reduction in cardiovascular risk (which randomized Yes Yes Very TH and the SOC-3 development project for 7 the chair of both the SOC-4 development project. Hes Stiffied of a period of time in which doctors and 1 It want to take you, though, specifically to 12 some family with enarrative in the medicial 13 It want to take you, though, specifically to 1 13 field of a period of time in which doctors and 13 I want to take you, though, specifically to 1 14 indeed guidelines were changed? 1 M. Suby aguely, and state stati th momen and subsequently those 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 <th></th> <th></th> <th></th> <th>Page 104</th>				Page 104	
3 handled the decision regarding hormone replacement 3 Coleman. Is that a name that means anything to you? 4 therapy (HRT) in postmenopausal women in the 1906; 5 A. No. 5 when observational studies suggested a substantial 6 Q. I will also represent to you that he was 6 trials subsequently proved false, at least in women 8 9 Valid also represent to you that he was 8 appreciably past menopausal, and equally low 9 Valence quality suggested an increase in the risk 9 of breast cancer (which proved true), "close quote. 10 Page - and he's testified that he is the author of 11 field of a period of time in which doctors and 14 indeed guidelines were recommending post-menopause. 16 nombers - and he's testified that he is the author of 11 I want to take you to Page - we call these 16 recommendations were changed? 16 A. Okay. 11 17 A. Only vaguely. 17 Ms. LFUE. It ends in 216. 18 18 Q. Any attain on a case study that 19 Q. Any attain at a name the work, attain any sort of conference? 21 No. <	1		1		
4 therapy (HRT) in postmenopausal women in the 1990s 4 A. No. 5 when observational studies suggested a substantial reduction in cardiovascular risk (which randomized risk) which randomized risk which randomized risk which randomized risk which rule, "close quote. 5 Q. I will also represent to you that he was 6 trains subsequently proved false, at least in women as paperciably past menopause), and equally low 9 Q. I will also represent to you that he was 10 of breast cancer (which proved rule," close quote. 10 Page - and he's testified that he is the author of 11 this entire 12-point plan written in February of 12 2023. My persentation. 13 field of a period of time in which doctors and 14 indeed guidelines were changed? 11 I want to take you, though, specifically to 10 Page - we call these 15 normone therapy for women, and subsequently those 15 normone therapy for women, and subsequently those 15 normone therapy for women, and subsequently those 15 normone therapy for women, and subsequently tory 22 2023. My representation. 10 Page - and he's testified that he is the author of 11 this entire 12-point plan written in February of 12 2023. My representation. 14 indeed guidelines were changed? 17 M. Okay, That's not a case study that 19 Q. And actually, the sentence at the pof 20 15 n. A. No. 10 A. Okay. 11 Do you see that? 21 in any sor	2		2		
5 when observational studies suggested a substantial 5 Q. I will also represent to you that he was 6 reduction in cardiovascular risk (which randomized risk suggested an increase in the risk appreciably past menopause), and equally low 6 the chair of both the SOC-7 development project for VPATH and the SOC-8 development project. He's testified about the substance. 9 evidence quality suggested an increase in the risk to of proved true). 'I close quote. 9 I want to take you, though, specifically to 10 10 of breast cancer (which the in which doctors and 14 indeed guidelines were recommending post-menopause). 10 Page - and he's testified that he is the author of 11 this entire 12-point plan written in February of 12 2023. My representation. 11 ant to take you to Page we call these 14 things at the bottom production numbers or Bates 15 hormone therapy for women, and subsequently those 16 A. Okay. 16 a. Ohy yauguly. 17 M. S. LEVI: It ends in 216. 18 19 A. No. 10 Wart to take you, thoody, syco know, 23 1995 I was really in pediatrics, and so by, you know, 23 1995 I was really in pediatrics, and fankly not yet 24 17 MS and twite, hereorer 10 10 Q. Nota focus of concern. Fair enough, 1 1 Do you see that? 2 <t< th=""><td>3</td><td></td><th>3</th><td></td></t<>	3		3		
6 reduction in cardiovascular risk (which randomized 6 the chair of both the SOC-7 development project for 7 trials subsequently proved false, at least in women 6 the chair of both the SOC-7 development project. He's 8 appreciably past menopause), and equally low 9 evidence quality suggested an increase in the risk. 10 of breast cancer (which proved true)," close quote. 10 Page and he's testified that he is the author of 11 Really my opening question is, do you have 11 this catter 12-point plant written in February of 12 2023. My representation. 12 2023. My representation. 13 Future to podiations were changed? 1 Man to take you to Page we call these 14 inded guidelines were changed? 1 M. Kaky out to Page we call these 15 hormoone therapy for women, and subsequently those 1 M. Kaky out to Page we call these 15 A. Only vaguely. 1 M. Subset call in the call in the inter school or 1 M. No. 20 Q you've been through in either school or 1 M. Kaky could and was 2 21 M. No. 2 Systemetaint aswe cotal have been (e.g., we did not	4		4		
7 trials subsequently proved false, at least in women 8 7 WPATH and the SOC-8 development project. He's 8 8 evidence quality suggested an increase in the risk 10 0 breast cancer (which proved true)," close quote. 11 Really my opening question is, do you have 12 0 10 Page - and he's testified about the substance. 13 field of a period of time in which doctors and 14 11 11 this entire 12-point plan written in February of 12 2023. My representation. 14 indeed guidelines were recommending post-menopause 15 hormone therapy for women, and subsequently those 16 12 2023. My representation. 15 hormone therapy for women, and subsequently those 16 numbers ending in 216. 16 A. Okay. 16 P. A. No. 9 Q. And actually, the sentence at the top of 20 Q. And actually, the sentence at the top of 20 10 Q. And actually, the sentence at the top of 20 10 Numbers - ending in 216. 21 in any sort of conference? 21 "As a result our methodology evolved and was 21 21 improve were not able to be as 23 23 systematic as we could have been (e.g., we did not 24 use GRADE explicitly)." 1 Q. Not afocus of concern. Fair enough. 1 1	5		5		
8 appreciably past menopause), and equally low 8 testified about the substance. 9 evidence quality suggested an increase in the risk. 10 I want to take you, though, specifically to 10 of breast cancer (which proved true), ''close quote. 10 Page - and hos t estified that he is the author of 11 Really my opening question is, do you have 11 The dot a period of time in which doctors and 14 indeed guidelines were recommending post-menopause 13 T want to take you to Page we call these 14 indeed guidelines were changed? 16 A. Okay. 17 A. Only vaguely. 17 MS. LEVI: It ends in 216. 18 Q. Okay. That's not a case study that 18 THE WITNESS: Okay. Got it. 19 A. No. 9 Q. And actually, the sentence at the top of 21 A. No went to pediatrics, and so by, you know. 23 systematic as we could have been (e.g., we did not 21 0. Not a focus of concern. Fair enough. I 2 A. Twat sall right. Ibrorght it up. 2 3 A. That's all right. Ibrorght it up. 9 Q. Not a focus of condernet mark of a signado confidential. Let me be clear 1 Do you see that?	6		6		
9 evidence quality suggested an increase in the risk 10 9 I want to take you, though, specifically to 10 11 Ikeally my opening question is, do you have 12 some familiarity with the narrative in the medical 13 field of a period of time in which doctors and 14 indeed guidelines were recommending post-menopause 15 induced guidelines were recommending post-menopause 15 1 I want to take you, though, specifically to 10 Page - we call these 14 16 recommendations were changed? 16 A. Okay. 17 MS. Okay. That's not a case study that 19 A. No. 10 Q. And actually, the sentence at the top of 20 Q you've been through in either school or 21 18 THE WITNESS: Okay. Got it. 18 17 MS. Device were not able to be as 23 24 23 A. Naver to pediatrics, and so by, you know, 23 1995 I was really in pediatrics and frankly not yet 24 10 a secult our methodology evolved and was 22 24 interps of conference? 11 10 Do you see that? 20 24 diah manto get personal. 3 3 A. That's all right. Ibrough it up. 4 4 Sometimes that's what you pay attention to. 5 3 Q. Now, the chairman of the SOC-8 projeet has 4 4 3 A. That's all right. Ibrough 12(b, which is an 8	7		7	· · · ·	
10 of breast cancer (which proved true)," close quote. 10 Page and he's testified that he is the author of 11 Really my opening question is, do you have 10 Page and he's testified that he is the author of 12 some familiarity with the narrative in the medical 11 this cantire 12-point plan written in February of 13 field of a period of time in which doctors and 11 this cantire 12-point plan written in February of 14 indeed guidelines were recommending post-menopause 14 indeed guidelines were changed? 16 A. Only vaguely. 16 A. Okay. 17 A. Only vaguely. 17 MS. LEVI: It ends in 216. 18 Q. Okay. That's not a case study that 19 Q. And actually, the sentence at the top of 20 Q you've been through in either school or 11 many sort of conference? 12 21 A. I went to pediatrics, and so by, you know, 23 systematic as we could have been (e.g., we did not 23 A. That's all right. I brought it up. 2 A. Yes. 3 3 A. That's all right. I brought it up. 2 A. Yes. 4 Sometines that's what you pay attention to.	8		8		
11 Really my opening question is, do you have 11 this entire 12-point plan written in February of 12 some familiarity with the narrative in the medical 11 this entire 12-point plan written in February of 13 field of a period of time in which doctors and 13 T want to take you to Page we call these 14 indeed guidelines were recommending post-menopause 14 this entire 12-point plan written in February of 15 hormone therapy for women, and subsequently those 15 numbers ending in 216. 16 recommendations were changed? 17 MS. LEVI: It ends in 216. 17 A. Only vaguely. 17 MS. LEVI: It ends in 216. 18 Q. Okay. That's not a case study that 18 THE WTINESS: Okay. Got it. 19 A. No. 19 Q. And actually, the sentence at the top of 21 in any sort of conference? 21 "As a result our methodology evolved and was 23 1995 It was realy in pediatrics and frankly not yet 24 was gRADE explicitly. 24 myself in menopause. So 1 Do you see that? 2 2 daint mean teap target onit was a stabib to a document bearing Bates 3	9				
12 some familiarity with the narrative in the medical 13 field of a period of time in which doctors and 13 field of a period of time in which doctors and 13 I want to take you to Page we call these 14 indeed guidelines were recommending post-menopause 14 things at the bottom production numbers or Bates 15 normone therapy for women, and subsequently those 14 things at the bottom production numbers or Bates 16 recommendations were changed? 16 A. Okay. 17 A. Only vaguely. 17 MS. LEVI: It ends in 216. 18 Q. Okay. That's not a case study that 19 Q. And actually, the sentence at the top of 20 Qyou've been through in either school or 11 The WITNESS: Okay. Got it. 21 in any sort of conference? 21 ''''''''''''''''''''''''''''''''''''	10		10	-	
13 field of a period of time in which doctors and 13 I want to take you to Page we call these 14 indeed guidelines were recommending post-menopause 15 things at the bottom production numbers or Bates 15 hormone therapy for women, and subsequently those 16 A. Okay. 17 A. Only vaguely. 16 A. Okay. 18 Q. Okay. That's not a case study that 19 A. No. 19 A. No. 17 MS. LEVI: It ends in 216. 16 may sort of conference? 20 Qyou've been through in either school or 21 in any sort of conference? 21 Naw really in pediatrics and frankly not yet 23 1995 I was really in pediatrics and frankly not yet 23 systematic as we could have been (e.g., we did not 21 Q. Not a focus of concern. Fair enough. I 2 A. That's all right. I brought it up. 3 4 Sometimes that's what you pay attention to. 3 Q. Now, the chairman of the SOC-8 project has 4 written, after the completion of that project, that 5 the team did not use GRADE explicitly. 5 MR. BKOOKS: Trn going to ask the reporter 6 Do you have any basis to disag	11		11		
14 indeed guidelines were recommending post-menopause 14 things at the bottom production numbers or Bates 15 hormone therapy for women, and subsequently those 15 numbers - ending in 216. 16 recommendations were changed? 16 A. Okay. 17 A. Only vaguely. 17 MS. LEVI: It ends in 216. 18 Q. Okay. That's not a case study that 18 THE WITNESS: Okay. Got it. 19 A. No. 19 Q. And actually, the sentence at the top of 20 Q you've been through in either school or 21 in any sort of conference? 20 21 in any sort of conference? 21 "As a result our methodology evolved and was 23 1995 I was really in pediatrics and frankly not yet 24 is a result our methodology evolved and was 24 myself in menopause. So Page 10 1 Do you see that? 2 A. That's all right. I brought it up. 3 Q. Now, the chairman of the SOC-8 project has 4 sometimes that's what you pay attention to. 5 the team did not use GRADE explicitly. 6 to mark as Exhibit 10 a document bearing Bates Q. Now, the chairman of the SOC-8 project has	12	•	12	• •	
15 hormone therapy for women, and subsequently those 15 numbers ending in 216. 16 A. Ohly vaguely. 16 A. Okay. 17 A. Only vaguely. 17 MS. LEVI: It ends in 216. 18 Q. Okay. That's not a case study that 18 THE WITNESS: Okay. Got it. 19 A. No. 19 Q. And actually, the sentence at the top of 20 Q you've been through in either school or 21 in any sort of conference? 21 in any sort of conference? 21 "As a result our methodology evolved and was 23 1995 I was really in pediatrics, and so by, you know, 23 systematic as we could have been (e.g., we did not 24 myself in menopause. So 24 use GRADE explicitly)." Page 10 1 Do you see that? 2 A. Yes. 3 Q. Now, the chairman of the SOC-8 project has 3 A. That's all right. Ibrough it up. 3 Q. Now, the chairman of the SOC-8 project has 4 Sometimes that's what you pay attention to. 5 MR. BROOKS: Im going to ask the reporter 6 Do you have any basis to disagree with him 7 numbers BOEAL_WPATH_91211 through 91218, which is an	13	field of a period of time in which doctors and	13	I want to take you to Page we call these	
16 recommendations were changed? 16 A. Only vaguely. 17 A. Only vaguely. 17 MS. LEVI: It ends in 216. 18 Q. Okay. That's not a case study that 19 A. No. 19 A. No. 10 Q. And actually, the sentence at the top of 20 Q you've been through in either school or 21 in any sort of conference? 21 A. I went to pediatrics, and so by, you know, 22 improved - however, we were not able to be as 21 195 I was really in pediatrics and frankly not yet 23 systematic as we could have been (e.g., we did not 24 myself in menopause. So Page 10 1 Do you see that? 2 didn't men to get personal. 3 Q. Now, the chairman of the SOC-8 project has 4 sometimes that's what you pay attention to. 3 Q. Now, the chairman of the SOC-8 project has 5 M. RBOOKS: I'm going to ask the reporter 6 Do you have any basis to disagree with him 6 that all right. Ibrough 1218, which is an 8 A. Obviously, I'm, like, just looking at this 9 Pehruary 7, attaching a "Darft 12-point Strategic 10 Q. He goes on to say, under "Research	14	indeed guidelines were recommending post-menopause	14	things at the bottom production numbers or Bates	
17A. Only vaguely.17MS. LEVI: It ends in 216.18Q. Okay. That's not a case study that19A. No.19A. No.MS. LEVI: It ends in 216.19A. No.MS. LEVI: It ends in 216.19A. No.Q you've been through in either school or21in any sort of conference?22A. I went to pediatrics, and so by, you know,231995 I was really in pediatrics and frankly not yet24myself in menopause. So24myself in menopause. So24myself in menopause. So24a focus of concern. Fair enough. I2didn't mean to get personal.3A. That's all right. I brought it up.4Sometimes that's what you pay attention to.5MR. BROOKS: I'm going to ask the reporter6to mark as Exhibit 10 a document bearing Bates7Numbers BOEAL_WPATH_91211 through 91218, which is an8email dated February 23 – February of 2023,9February 7, attaching a "Draft 12-poin Strategic10on the record.12(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate15the transcript as confidential.16MR. BROOKS: And I will ask you to follow17up with specific designations within that. I think18this may be the only confidential document we'll19look at.20MS. LEVI: Okay.21Q. Dr. Light	15	hormone therapy for women, and subsequently those	15	numbers ending in 216.	
18 Q. Okay. That's not a case study that 18 THE WITNESS: Okay. Got it. 19 A. No. 20 Qyou've been through in either school or 21 in any sort of conference? 21 in any sort of conference? 21 "As a result our methodology evolved and was 22 A. I went to pediatrics, and so by, you know, 21 "As a result our methodology evolved and was 23 1995 I was really in pediatrics and frankly not yet 23 systematic as we could have been (e.g., we did not 24 myself in menopause. So Page 103 Page 103 1 Do you see that? 2 A. Tat's all right. I brough it up. 3 3 A. That's all right. I brough it up. 3 Q. Now, the chairman of the SOC-8 project has 4 Sometimes that's what you pay attention to. 5 MR_BROOKS: Tm going to ask the reporter 6 6 to mark as Exhibit 10 a document bearing Bates 7 Numbers BOEAL_WPATH_91211 through 91218, which is an 8 8 enail datel February 23 - February 6123. February 7, attaching a "Draft 12-point Strategic 10 10 nu he record. 12 Obcoument marked as Lightdale 13 Exhibiti 10	16	recommendations were changed?	16	A. Okay.	
19 A. No. 19 A. No. 20 Qyou've been through in either school or 21 in any sort of conference? 22 A. I went to pediatrics, and so by, you know, 23 199 Q. And actually, the sentence at the top of 20 A. I went to pediatrics, and so by, you know, 199 23 1995 I was really in pediatrics and frankly not yet 24 24 myself in menopause. So 23 7 Page 103 Page 103 1 Q. Not a focus of concern. Fair enough. 1 2 2 didn't mean to get personal. 3 3 A. That's all right. Ibrought it up. 4 4 Sometimes that's what you pay attention to. 5 5 MR. BROOKS: I'm going to ask the reporter 6 6 to mark as Exhibit 10 a document bearing Bates 7 7 Numbers BOEAL_WPATH_91211 through 91218, which is an 8 8 enaid dated February 23 - February 6123, egread" pardon me. Let me just draw your 12 (Document marked as Lightdale 13 13 Exhibit 10 for identiffication) 14 <td< th=""><td>17</td><td>A. Only vaguely.</td><th>17</th><td>MS. LEVI: It ends in 216.</td></td<>	17	A. Only vaguely.	17	MS. LEVI: It ends in 216.	
20 Q you've been through in either school or 20 the page begins at the bottom of 215 where he wrote, 21 in any sort of conference? 20 the page begins at the bottom of 215 where he wrote, 22 A. I went to pediatrics, and so by, you know, 21 "As a result our methodology evolved and was 23 1995 I was really in pediatrics and frankly not yet 23 systematic as we could have been (e.g., we did not 24 myself in menopause. So Page 103 Page 103 1 Q. Not a focus of concern. Fair enough.1 2 A. That's all right. I brought it up. 2 A. That's all right. I brought it up. 3 Q. Now, the chairman of the SOC-8 project has 4 Sometimes that's what you pay attention to. 5 MR. BROOKS: I'm going to ask the reporter 6 Do you have any basis to disagree with him 6 to mark as Exhibit 10 a document bearing Bates 7 Numbers BOEAL_WPATH_91211 through 91218, which is an 8 A. Obviously, I'm, like, just looking at this 9 rebruary 7, attaching a "Draft 12-point Strategic 0 Q. He goes on to say, under "Research 10 n the record. 12 (Document marked as Lightdale 13 ending in 216, where he says, quote, "I th	18	Q. Okay. That's not a case study that	18	THE WITNESS: Okay. Got it.	
21 in any sort of conference? 21 "As a result our methodology evolved and was 22 A. I went to pediatrics, and so by, you know, 23 improved - however, we were not able to be as 23 1995 I was really in pediatrics and frankly not yet 24 improved - however, we were not able to be as 24 myself in menopause. So Page 10 24 use GRADE explicitly." 1 Q. Not a focus of concern. Fair enough. I 2 A. Yes. 3 Q. Now, the chairman of the SOC-8 project has 4 Sometimes that's what you pay attention to. 5 MR. BROOKS: I'm going to ask the reporter 6 Do you have any basis to disagree with him 7 Numbers BOEAL_WPATH_91211 through 91218, which is an 8 written, after the completion of that project, that 5 MR. BROOKS: I'm going to ask the reporter 6 Do you have any basis to disagree with him 7 numbers BOEAL_WPATH_91211 through 91218, which is an 8 M. Obviously, I'm, like, just looking at this 9 February 7, attaching a 'Draft 12-point Strategic 10 Q. He goes on to say, under "Research 11 on the record. 11 Agenda'' pardon me. Let me just draw your 12 (Document ma	19	A. No.	19	Q. And actually, the sentence at the top of	
22 A. I went to pediatrics, and so by, you know, 22 improved - however, we were not able to be as 23 1995 I was really in pediatrics and frankly not yet 23 systematic as we could have been (e.g., we did not 24 myself in menopause. So Page 103 Page 10 Page 103 Page 10 Page 10 <td colsp<="" th=""><td>20</td><td>Q you've been through in either school or</td><th>20</th><td>the page begins at the bottom of 215 where he wrote,</td></td>	<td>20</td> <td>Q you've been through in either school or</td> <th>20</th> <td>the page begins at the bottom of 215 where he wrote,</td>	20	Q you've been through in either school or	20	the page begins at the bottom of 215 where he wrote,
23 1995 I was really in pediatrics and frankly not yet 23 systematic as we could have been (e.g., we did not 24 myself in menopause. So 24 use GRADE explicitly)." Page 103 1 Q. Not a focus of concern. Fair enough. I 24 use GRADE explicitly)." 2 didn't mean to get personal. 3 A. That's all right. I brough it up. 3 Q. Now, the chairman of the SOC-8 project has 4 Sometimes that's what you pay attention to. 5 MR. BROOKS: Tm going to ask the reporter 6 Do you have any basis to disagree with him 5 MR. BROOKS: The going to ask the reporter 6 Do you have any basis to disagree with him 7 numbers BOEAL_WPATH_91211 through 91218, which is an 8 A. Obviously, I'm, like, just looking at this 9 February 7, attaching a "Draft 12-point Strategic 10 Q. He goes on to say, under "Research 11 on the record. 11 A. Obviously, I'm, like, just looking at this 12 (Document marked as Lightdale 13 ending in 216, where he says, quote, "I think it 13 the transcript as confidential. 14 MS. LEVI: Roger, we're going to designate 15 expert or experts to exami	21	in any sort of conference?	21		
24 use GRADE explicitly)." Page 103 Page 103 1 Q. Not a focus of concern. Fair enough. I 1 Do you see that? 2 didn't mean to get personal. 3 A. That's all right. 1 brought it up. 3 A. That's all right. 1 brought it up. 3 Q. Now, the chairman of the SOC-8 project has 4 Sometimes that's what you pay attention to. 5 MR. BROOKS: I'm going to ask the reporter 6 to mark as Exhibit 10 a document bearing Bates 7 Numbers BOEAL_WPATH_91211 through 91218, which is an 8 email dated February 23 February of 2023, 6 Do you have any basis to disagree with him 7 in that regard? 8 A. Obviously, I'm, like, just looking at this 9 February 7, attaching a "Draft 12-point Strategic 10 Q. He goes on to say, under "Research 11 on the record. 11 Agenda" pardon me. Let me just draw your 12 (Document marked as Lightdale 13 ending in 216, where he says, quote, "I think it 13 Exhibit 10 for identification) 14 Would be helpful to engage a guideline development 14 MS. LEVI: Roger, we're going to designate 15 exper	22	A. I went to pediatrics, and so by, you know,	22	improved - however, we were not able to be as	
Page 103Page 103Page 1031Q. Not a focus of concern. Fair enough. I1Do you see that?2didn't mean to get personal.3A. That's all right. I brought it up.34Sometimes that's what you pay attention to.3Q. Now, the chairman of the SOC-8 project has4Sometimes that's what you pay attention to.3Q. Now, the chairman of the SOC-8 project has5MR. BROOKS: I'm going to ask the reporter6to mark as Exhibit 10 a document bearing Bates7Numbers BOEAL_WPATH_91211 through 91218, which is an8email dated February 23 - February of 2023,9February 7, attaching a "Draft 12-point Strategic0Q. Uhe goes on to say, under "Research10Plan," and designated confidential. Let me be clear10Q. He goes on to say, under "Research11on the record.11Agenda" pardon me. Let me just draw your12(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate15expert or experts to examine what we have done and16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think19strengths. At the same time, we need to know its20MS. LEVI: Roky.21Do you see that?21Q. Dr. Lightdale, I'm confident you have not22A. Yes.22A. No.23Q. Do you consider it good practice to develop <td>23</td> <td>1995 I was really in pediatrics and frankly not yet</td> <th>23</th> <td>systematic as we could have been (e.g., we did not</td>	23	1995 I was really in pediatrics and frankly not yet	23	systematic as we could have been (e.g., we did not	
1Q. Not a focus of concern. Fair enough. I2didn't mean to get personal.3A. That's all right. I brought it up.4Sometimes that's what you pay attention to.5MR. BROOKS: I'm going to ask the reporter6to mark as Exhibit 10 a document bearing Bates7Numbers BOEAL_WPATH_91211 through 91218, which is an8email dated February 23 February of 2023,9Februar 7, attaching a "Draft 12-point Strategic10Plan," and designated confidential. Let me be clear11on the record.12(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate15the transcript as confidential.16MR. BROOKS: And I will ask you to follow17up with specific designations within that. I think18this may be the only confidential document we'll19look at.20MS. LEVI: Okay.21Q. Dr. Lightdale, I'm confident you have not22seen this before.23A. No.24A. No.	24	myself in menopause. So	24	use GRADE explicitly)."	
2didn't mean to get personal.2A. Yes.3A. That's all right. I brought it up.2A. Yes.4Sometimes that's what you pay attention to.5MR. BROOKS: I'm going to ask the reporter6to mark as Exhibit 10 a document bearing Bates7Numbers BOEAL_WPATH_91211 through 91218, which is an8email dated February 23 February of 2023,6Do you have any basis to disagree with him9February 7, attaching a "Draft 12-point Strategic9He goes on to say, under "Research10Plan," and designated confidential. Let me be clear10Q. He goes on to say, under "Research11on the record.11Agenda" pardon me. Let me just draw your12(Document marked as Lightdale13ending in 216, where he says, quote, "I think it14MS. LEVI: Roger, we're going to designate15expert or experts to examine what we have done and16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think18to say, "We need to sharpen our method about19look at.20MS. LEVI: Okay.2120MS. LEVI: Okay.21Do you usee that?21Q. Dr. Lightdale, I'm confident you have not22A. Yes.23A. No.23Q. Do you consider it good practice to develop		Page 103		Page 105	
3A. That's all right. I brough it up.3A. That's all right. I brough it up.4Sometimes that's what you pay attention to.5MR. BROOKS: I'm going to ask the reporter6to mark as Exhibit 10 a document bearing Bates7Numbers BOEAL_WPATH_91211 through 91218, which is an8email dated February 23 February of 2023,9February 7, attaching a "Draft 12-point Strategic10Plan," and designated confidential. Let me be clear11on the record.12(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate15the transcript as confidential.16MR. BROOKS: And I will ask you to follow17up with specific designations within that. I think18this may be the only confidential document we'll19look at.20MS. LEVI: Okay.21Q. Dr. Lightdale, I'm confident you have not22seen this before.23A. No.	1	Q. Not a focus of concern. Fair enough. I	1	Do you see that?	
4Sometimes that's what you pay attention to.4written, after the completion of that project, that5MR. BROOKS: I'm going to ask the reporter6to mark as Exhibit 10 a document bearing Bates7Numbers BOEAL_WPATH_91211 through 91218, which is an8mail dated February 23 February of 2023,8Remail dated February 23 February of 2023,8A. Obviously, I'm, like, just looking at this9February 7, attaching a "Draft 12-point Strategic9But that is what is written there.10Plan," and designated confidential. Let me be clear10Q. He goes on to say, under "Research11on the record.11Agenda" pardon me. Let me just draw your12(Document marked as Lightdale13ending in 216, where he says, quote, "I think it14MS. LEVI: Roger, we're going to designate14would be helpful to engage a guideline development15the transcript as confidential.11strengths. At the same time, we need to know its19look at.19strengths. At the same time, we need to know its20MS. LEVI: Okay.21Do you consider it good practice to develop21Q. Dr. Lightdale, I'm confident you have not22A. Yes.23A. No.23Q. Do you consider it good practice to develop	2	didn't mean to get personal.	2	A. Yes.	
5MR. BROOKS: Tm going to ask the reporter5the team did not use GRADE explicitly.6to mark as Exhibit 10 a document bearing Bates7Do you have any basis to disagree with him7Numbers BOEAL_WPATH_91211 through 91218, which is an6Do you have any basis to disagree with him8email dated February 23 February of 2023,8A. Obviously, I'm, like, just looking at this9February 7, attaching a "Draft 12-point Strategic10Q. He goes on to say, under "Research11on the record.11Agenda" pardon me. Let me just draw your12(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate14would be helpful to engage a guideline development15the transcript as confidential.14would be helpful to engage a guideline development16MR. BROOKS: And I will ask you to follow17what we have done." And he goes on a little farther18this may be the only confidential document we'll19strengths. At the same time, we need to know its20MS. LEVI: Okay.21Do you see that?21Q. Dr. Lightdale, I'm confident you have not22A. Yes.23A. No.23Q. Do you consider it good practice to develop	3	A. That's all right. I brought it up.	3	Q. Now, the chairman of the SOC-8 project has	
6to mark as Exhibit 10 a document bearing Bates6Do you have any basis to disagree with him7Numbers BOEAL_WPATH_91211 through 91218, which is an6Do you have any basis to disagree with him8email dated February 23 - February of 2023,8A. Obviously, I'm, like, just looking at this9February 7, attaching a "Draft 12-point Strategic9thing. But that is what is written there.10Plan," and designated confidential. Let me be clear10Q. He goes on to say, under "Research11on the record.11Agenda" pardon me. Let me just draw your12(Document marked as Lightdale13ending in 216, where he says, quote, "I think it14MS. LEVI: Roger, we're going to designate14would be helpful to engage a guideline development15the transcript as confidential.1think16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think18to say, "We need to sharpen our method about19look at.20MS. LEVI: Okay.2120MS. LEVI: Okay.21Do you see that?21Q. Dr. Lightdale, I'm confident you have not22A. Yes.23A. No.23Q. Do you consider it good practice to develop	4	Sometimes that's what you pay attention to.	4	written, after the completion of that project, that	
7Numbers BOEAL_WPATH_91211 through 91218, which is an8email dated February 23 February of 2023,9February 7, attaching a "Draft 12-point Strategic10Plan," and designated confidential. Let me be clear11on the record.12(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate15the transcript as confidential.16MR. BROOKS: And I will ask you to follow17up with specific designations within that. I think18this may be the only confidential document we'll19look at.20MS. LEVI: Okay.21Q. Dr. Lightdale, I'm confident you have not22seen this before.23A. No.	5	MR. BROOKS: I'm going to ask the reporter	5	the team did not use GRADE explicitly.	
8email dated February 23 February of 2023,99February 7, attaching a "Draft 12-point Strategic910Plan," and designated confidential. Let me be clear1011on the record.1012(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate15the transcript as confidential.16MR. BROOKS: And I will ask you to follow17up with specific designations within that. I think18this may be the only confidential document we'll19look at.20MS. LEVI: Okay.21Q. Dr. Lightdale, I'm confident you have not22seen this before.23A. No.	6	to mark as Exhibit 10 a document bearing Bates	6	Do you have any basis to disagree with him	
9February 7, attaching a "Draft 12-point Strategic9thing. But that is what is written there.10Plan," and designated confidential. Let me be clear10Q. He goes on to say, under "Research11on the record.11Agenda" pardon me. Let me just draw your12(Document marked as Lightdale12attention to the first full paragraph on the page13Exhibit 10 for identification)13ending in 216, where he says, quote, "I think it14MS. LEVI: Roger, we're going to designate15the transcript as confidential.16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think14to say, "We need to sharpen our method about19look at.20MS. LEVI: Okay.2121Q. Dr. Lightdale, I'm confident you have not22A. Yes.23A. No.23Q. Do you consider it good practice to develop	7	Numbers BOEAL_WPATH_91211 through 91218, which is an	7	in that regard?	
10Plan," and designated confidential. Let me be clear11on the record.12(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate15the transcript as confidential.16MR. BROOKS: And I will ask you to follow17up with specific designations within that. I think18this may be the only confidential document we'll19look at.20MS. LEVI: Okay.21Q. Dr. Lightdale, I'm confident you have not22seen this before.23A. No.	8	email dated February 23 February of 2023,	8	A. Obviously, I'm, like, just looking at this	
11on the record.11Agenda" pardon me. Let me just draw your12(Document marked as Lightdale12attention to the first full paragraph on the page13Exhibit 10 for identification)13ending in 216, where he says, quote, "I think it14MS. LEVI: Roger, we're going to designate14would be helpful to engage a guideline development15the transcript as confidential.15expert or experts to examine what we have done and16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think17what we have done." And he goes on a little farther18this may be the only confidential document we'll19strengths. At the same time, we need to know its20MS. LEVI: Okay.21Do you see that?21Q. Dr. Lightdale, I'm confident you have not21Do you consider it good practice to develop23A. No.23Q. Do you consider it good practice to develop	9	February 7, attaching a "Draft 12-point Strategic	9	thing. But that is what is written there.	
12(Document marked as Lightdale13Exhibit 10 for identification)14MS. LEVI: Roger, we're going to designate15the transcript as confidential.16MR. BROOKS: And I will ask you to follow17up with specific designations within that. I think18this may be the only confidential document we'll19look at.20MS. LEVI: Okay.21Q. Dr. Lightdale, I'm confident you have not22seen this before.23A. No.24Mo.25Max26Max27Q. Dr. Lightdale, I'm confident you have not28Q. Do you consider it good practice to develop29A. No.20Do you consider it good practice to develop20MS. LEVI: Okay.21Do you consider it good practice to develop22A. No.23Q. Do you consider it good practice to develop	10	Plan," and designated confidential. Let me be clear	10	Q. He goes on to say, under "Research	
13Exhibit 10 for identification)13ending in 216, where he says, quote, "I think it14MS. LEVI: Roger, we're going to designate13ending in 216, where he says, quote, "I think it15the transcript as confidential.14would be helpful to engage a guideline development16MR. BROOKS: And I will ask you to follow15expert or experts to examine what we have done and16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think17what we have done." And he goes on a little farther18this may be the only confidential document we'll18to say, "We need to sharpen our method about19look at.19strengths. At the same time, we need to know its20MS. LEVI: Okay.21Do you see that?2122A. Yes.2323A. No.23Q. Do you consider it good practice to develop	11	on the record.	11	Agenda" pardon me. Let me just draw your	
14MS. LEVI: Roger, we're going to designate14would be helpful to engage a guideline development15the transcript as confidential.14would be helpful to engage a guideline development16MR. BROOKS: And I will ask you to follow15expert or experts to examine what we have done and16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think17what we have done." And he goes on a little farther18this may be the only confidential document we'll18to say, "We need to sharpen our method about19look at.19strengths. At the same time, we need to know its20MS. LEVI: Okay.21Do you see that?21Q. Dr. Lightdale, I'm confident you have not21Do you consider it good practice to develop23A. No.23Q. Do you consider it good practice to develop	12	(Document marked as Lightdale	12	attention to the first full paragraph on the page	
15the transcript as confidential.15expert or experts to examine what we have done and16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think16help us form a clear narrative and justification for18this may be the only confidential document we'll18to say, "We need to sharpen our method about19look at.19strengths. At the same time, we need to know its20MS. LEVI: Okay.20limitations."21Q. Dr. Lightdale, I'm confident you have not21Do you see that?22seen this before.22A. Yes.23A. No.23Q. Do you consider it good practice to develop	13	Exhibit 10 for identification)	13	ending in 216, where he says, quote, "I think it	
16MR. BROOKS: And I will ask you to follow16help us form a clear narrative and justification for17up with specific designations within that. I think16help us form a clear narrative and justification for18this may be the only confidential document we'll16help us form a clear narrative and justification for19look at.17what we have done." And he goes on a little farther19look at.18to say, "We need to sharpen our method about19look at.19strengths. At the same time, we need to know its20MS. LEVI: Okay.20limitations."21Q. Dr. Lightdale, I'm confident you have not21Do you see that?22seen this before.22A. Yes.23A. No.23Q. Do you consider it good practice to develop	14	MS. LEVI: Roger, we're going to designate	14	would be helpful to engage a guideline development	
17up with specific designations within that. I think18this may be the only confidential document we'll19look at.20MS. LEVI: Okay.21Q. Dr. Lightdale, I'm confident you have not22seen this before.23A. No.	15	the transcript as confidential.	15	expert or experts to examine what we have done and	
18this may be the only confidential document we'll18to say, "We need to sharpen our method about19look at.19strengths. At the same time, we need to know its20MS. LEVI: Okay.20limitations."21Q. Dr. Lightdale, I'm confident you have not21Do you see that?22seen this before.22A. Yes.23A. No.23Q. Do you consider it good practice to develop	16	MR. BROOKS: And I will ask you to follow	16	help us form a clear narrative and justification for	
19 look at.19 strengths. At the same time, we need to know its20MS. LEVI: Okay.21Q. Dr. Lightdale, I'm confident you have not22 seen this before.2123A. No.24Do you consider it good practice to develop25C. Do you consider it good practice to develop	17	up with specific designations within that. I think	17	what we have done." And he goes on a little farther	
20MS. LEVI: Okay.20limitations."21Q. Dr. Lightdale, I'm confident you have not21Do you see that?22seen this before.22A. Yes.23A. No.23Q. Do you consider it good practice to develop	18	this may be the only confidential document we'll	18	to say, "We need to sharpen our method about	
21Q. Dr. Lightdale, I'm confident you have not21Do you see that?22seen this before.22A. Yes.23A. No.23Q. Do you consider it good practice to develop	19	look at.	19	strengths. At the same time, we need to know its	
22 seen this before.22A. Yes.23A. No.23Q. Do you consider it good practice to develop	20	MS. LEVI: Okay.	20	limitations."	
23 A. No. 23 Q. Do you consider it good practice to develop	21	Q. Dr. Lightdale, I'm confident you have not	21	Do you see that?	
	1	41.1.6	22	A. Yes.	
24 Q. I will represent to you that discovery and 24 and publish guidelines and afterwards bring in an	22	seen this before.			

27 (Pages 102 - 105)

1	Page 106	1	Page 108
	expert to help you know the limitations of what	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	So what they seem to be saying here is that
	you've done?	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	Hopkins was helpful, but also constraining, and it's
3	MS. LEVI: Object as to form.	3	like, "Oh, maybe we could have gone about this a
4	A. I think I need to understand the context of	4	different way."
	this. Is he talking about "We were not able to	5	And so now they're saying, you know I
6	be as systematic as we could have been," is he	6	mean, he's saying, "We're being attacked for the
7	talking about SOC-7, and now they're trying to say	7	methodology." Obviously I'm sitting here today
	how are they going to improve things with SOC-8?	8	trying to understand what we're being asked but
9	Q. If you look at the beginning of that	9	they said, "Okay, how can we continue to think about
10	paragraph, I believe this is my understanding,	10	what we've done."
11	not a representation that this is discussing what	11	So I don't think it's wrong to bring in
	was actually done in SOC-8.	12	somebody to say, "Okay, here's what we've done.
13	A. Okay. Yes. So	13	What do you think of it? And can you" you know,
14	Q. Do you want to hear my question back?	14	I guess here they're saying, "Can you help us feel
15	MS. LEVI: And also you should take the	15	good about what we did, because we were trying to be
	time if you need to review the document.	16	as robust as we possibly could be," which takes a
17	THE WITNESS: Yeah, yeah. Let me	17	lot of work.
	understand where this is, because obviously I'm,	18	Q. Understood.
	like I don't know timelines, et cetera.	19	MR. BROOKS: Let me ask the reporter to
20	A. (Reviewing document)	20	mark as Exhibit 11 a paper by Taylor and others
21	Q. As far as timeline, I will represent to you	21	entitled "Clinical guidelines for children and
	that this is written after SOC-8 has been published.	22	adolescents experiencing gender dysphoria," dated
23	A. Okay. (Reviewing document) Can you repeat	23	2024.
24	your question.	24	
	$P_{}$ 107		
	Page 107		Page 109
1	Q. Yes. Do you consider it good practice for	1	(Document marked as Lightdale
2	Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines	1 2	(Document marked as Lightdale Exhibit 11 for identification)
2 3	Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the		(Document marked as Lightdale Exhibit 11 for identification)Q. Dr. Lightdale, this is obviously a recently
2 3	Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used?	2	(Document marked as Lightdale Exhibit 11 for identification)Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the
2 3	Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form.	2 3	(Document marked as Lightdale Exhibit 11 for identification)Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating
2 3 4	Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used?	2 3 4	(Document marked as Lightdale Exhibit 11 for identification)Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the
2 3 4 5 6 7	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading 	2 3 4 5	(Document marked as Lightdale Exhibit 11 for identification)Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating
2 3 4 5 6 7 8	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't 	2 3 4 5 6	(Document marked as Lightdale Exhibit 11 for identification)Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and
2 3 4 5 6 7 8 9	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we 	2 3 4 5 6 7 8 9	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent
2 3 4 5 6 7 8 9 10	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was 	2 3 4 5 6 7 8	(Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and
2 3 4 5 6 7 8 9 10	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we 	2 3 4 5 6 7 8 9	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent
2 3 4 5 6 7 8 9 10 11 12	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what 	2 3 4 5 6 7 8 9 10	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first
2 3 4 5 6 7 8 9 10 11 12 13	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, 	2 3 4 5 6 7 8 9 10 11	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind
2 3 4 5 6 7 8 9 10 11 12 13 14	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. 	2 3 4 5 6 7 8 9 10 11 12	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like 	2 3 4 5 6 7 8 9 10 11 12 13	(Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like even in you've been giving me some of this GRADE 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines."
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like even in you've been giving me some of this GRADE stuff. There is this concern and I think I wrote 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines." Now, you looked at a methodology web page,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like even in you've been giving me some of this GRADE stuff. There is this concern and I think I wrote about this in my own thing there is this concern 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines." Now, you looked at a methodology web page, but just to be clear on the record, you have not
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like even in you've been giving me some of this GRADE stuff. There is this concern and I think I wrote about this in my own thing there is this concern that GRADE itself, especially in pediatrics, can 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	(Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines." Now, you looked at a methodology web page, but just to be clear on the record, you have not undertaken any attempt to apply the AGREE II
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like even in you've been giving me some of this GRADE stuff. There is this concern and I think I wrote about this in my own thing there is this concern that GRADE itself, especially in pediatrics, can lead us to almost not give the right strong 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines." Now, you looked at a methodology web page, but just to be clear on the record, you have not undertaken any attempt to apply the AGREE II methodologies or I should say criteria to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like even in you've been giving me some of this GRADE stuff. There is this concern and I think I wrote about this in my own thing there is this concern that GRADE itself, especially in pediatrics, can lead us to almost not give the right strong recommendations we need to, because we just don't 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	(Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines." Now, you looked at a methodology web page, but just to be clear on the record, you have not undertaken any attempt to apply the AGREE II methodologies or I should say criteria to evaluate the WPATH guidelines, correct?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like even in you've been giving me some of this GRADE stuff. There is this concern and I think I wrote about this in my own thing there is this concern that GRADE itself, especially in pediatrics, can lead us to almost not give the right strong recommendations we need to, because we just don't have the evidence that GRADE is assuming is on the 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 (Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines." Now, you looked at a methodology web page, but just to be clear on the record, you have not undertaken any attempt to apply the AGREE II methodologies or I should say criteria to evaluate the WPATH guidelines, correct? A. Correct.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	 Q. Yes. Do you consider it good practice for a team to develop, finalize and publish guidelines and then seek expert input to understand the limitations of the methodology that they used? MS. LEVI: Object as to form. A. To be honest, there could be even more rigor around what happened. But as I'm reading this and you start at the beginning of, I don't know, Point 6, I guess, where it says, you know, "we had to rely on Johns Hopkins," which I'll assume was the methodologist, "which while some degree helpful, was very constraining." And I think that is what many people find. I don't know what Johns Hopkins did. But if you try, and even I feel like even in you've been giving me some of this GRADE stuff. There is this concern and I think I wrote about this in my own thing there is this concern that GRADE itself, especially in pediatrics, can lead us to almost not give the right strong recommendations we need to, because we just don't 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	(Document marked as Lightdale Exhibit 11 for identification) Q. Dr. Lightdale, this is obviously a recently published paper, which purports to evaluate the quality of a number of different guidelines relating to gender dysphoria in children and adolescents and goes through various detail and comes to various conclusions. Let me ask you this. And I can represent to you or you can turn to any of several pages and see that they refer to the AGREE II well, turn to Page 5, if you would, and you will see in the first column, the first full paragraph describes the kind of punchline table of this paper, and it says it shows "the AGREE II domain scores for the appraised guidelines." Now, you looked at a methodology web page, but just to be clear on the record, you have not undertaken any attempt to apply the AGREE II methodologies or I should say criteria to evaluate the WPATH guidelines, correct?

28 (Pages 106 - 109)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 30 of 58

CONFIDENTIAL

Page 110	Page 112
1 A. Correct. 1 safety discussions.	-
2 Q. Okay. Then I will not ask you to read that 2 So it was doing a syste	ematic review of
3 one. 3 anything out there, and then	a meta-analysis of the
4 And certainly you have not attempted to 4 randomized controlled trials	that did exist around
5 evaluate the body of evidence relied on for any 5 capnography, to begin to un	derstand just how big a
6 recommendation in SOC-8 to form your own view as to 6 study you'd need to do to sh	ow somebody dying,
7 whether that body of evidence is strong, moderate, 7 basically, and in the process	also showing, across
8 weak or very weak, have you? 8 all the studies, that monitori	ng with capnography
9 A. No. 9 does lead to less oxygen des	saturation.
10 Q. Do clinical practice guidelines themselves 10 Q. And so underlying th	is paper, your team did
11 constitute scientific evidence? 11 a formal systematic review?	, , , , , , , , , , , , , , , , , , , ,
12 MS. LEVI: Object as to form. 12 A. Yes.	
13 A. No, not per se. 13 Q. And you disclosed th	e I'm not even sure
14 Q. I will not take your time further with that 14 of the right term, but the PIG	
15 document. 15 think you said it earlier, but	
16 MR. BROOKS: I'm goings to ask the reporter 16 spell out what PICO stands	for.
17 to mark as Exhibit 12 a paper, the first author 17 A. PICO is the population	
18 Saunders and the last author Lightdale you've 18 what's the C and then O is	s outcomes.
19 moved into the senior slot there entitled 19 Q. All right. And did yo	ou make available,
20 "Patient safety during procedural sedation," and it 20 either in the paper or in pub	licly available
21 goes on, published in BMJ 21 supplemental material, evide	ence tables?
22 Q. Am I correct that's the British Medical 22 MS. LEVI: Object as	to form.
23 Journal 23 A. The truth is, I don't re	emember. I will
24 A. Yes. 24 tell you the first author, who	I worked with very
Page 111	Page 113
1 MR. BROOKS: in 2017. 1 closely on this, was a he's	-
2 (Document marked as Lightdale 2 just does health economics a	
3 Exhibit 12 for identification) 3 Q. On Page 2, you ident	ify let me take you
4 Q. And, Dr. Lightdale, for context, am I 4 down to the "Methods." Yo	u identified which
5 correct that the BMJ is really in the very top tier 5 databases you searched in, c	correct?
6 of respected medical journals in the world? 6 A. Yes.	
7 A. I would like to think so. I felt that 7 Q. And there's only three	e, but are these three
8 about getting the paper accepted. 8 so extensive that that represe	ents a rather
9 Q. That's nice to say, but more generally, am 9 comprehensive search?	
10 I correct that it is widely recognized as one of the 10 A. Yeah.	
11most respected medical journals?11Q. And it goes on to say	that the searches
12 MS. LEVI: Object as to form. 12 aimed to identify, quote, "al	
13A. Uh-huh.13on randomized, controlled to	rials," close quote.
14Q. And explain to me the nature of your14Let me ask, why did y	ou limit the search to
15 involvement in this paper.15 controlled trials?	
16A. So I served as the senior author on this16A. So at the time that we	
17 paper that involved several experts, as well as17 at that point, been a number	
18myself, in a particular monitoring technique called18controlled trials on capnogra	
19 capnography that clearly shows I mean, there are19 the first to do a randomized	
20 many studies out there that have shown that it can 20 capnography, and people die	_
21 pick up patients who are starting to desaturate in 21 their guidelines, which was	-
22 terms of oxygen. But, thankfully, none of the22 the time. I was very young	
23 studies alone have been big enough that anybody has 23 thought it would be a New H	-
24 become truly injured or died, you know, real patient 24 Medicine paper, but it wasn	't. it was pediatrics. It

29 (Pages 110 - 113)

	Page 114		Page 116
1	was okay. I learned a lot.	1	that are equally good at mitigating bias. So
2	But I will tell you then people when on	2	Q. Equally good?
3	and used my methodology and tried randomized you	3	A. Yeah. Maybe even better. So randomized
4	know, did randomized controlled trials in a number	4	controlled trials can introduce systematic biases if
5	of other populations. And this study took basically	5	you're not careful. I mean, just because something
6	any randomized controlled trial we could find and	6	is controlled doesn't mean it gets away from, you
7	was able to do a meta-analysis, so look at all the	7	said, the placebo effect or other things like that.
8	data across all the different trials.	8	It doesn't it's one way of designing a trial to
9	Q. Is it in fact the case, in your judgment,	9	try to mitigate that, but there's lots of ways to do
10	that uncontrolled studies are known to be at risk of	10	it.
11	serious bias as a result of effects such as the	11	Q. It says, a little bit lower down, quote,
12	placebo affect or confounding variables?	12	"Grey' or unpublished literature (including
13	MS. LEVI: Object as to form.	13	Congress abstracts) was included in the search
14	A. So study design is obviously critical to	14	strategy."
15	trying to get at whether or not intervention is	15	Do you see that?
16	going to be you know, can lead to the clinical	16	A. Yes.
17	outcome you're looking for. And there are different	17	Q. Now, am I correct that grey literature are
18	study designs you could use to try to mitigate bias.	18	publications that are have not been peer
19	I think the randomized controlled trial	19	reviewed? Is that what the term refers to?
20	design in this question was able to get away from	20	A. There is a definition for it, but, you
21	the question of bias in terms of there are other	21	know, for me, it's yes, for me, it's stuff that
22	ways to assess whether or not a patient's in	22	hasn't yet gone through the peer review process.
23	trouble.	23	Q. Why did you consider it appropriate to
24	So, really, you had to do a randomized	24	include grey literature in your search, if it has
	Page 115		Page 117
1	controlled trial in a creative way, which, again, I	1	not yet been through the peer review process?
2	was able to come up with a methodology that then	2	A. So this particular paper, we were
3	other people were able to use, where you could sort	3	determined to be as inclusive as possible and
4	of still have all the regular ways of monitoring	4	include anything that was out there that hadn't yet
5	patients nobody wants to have a procedure without	5	made it all the way to publication.
6	being monitored to make sure they don't, you know,	6	Q. And is it in fact commonly done, in
7	die and so we basically needed a randomized	7	systematic reviews, to include grey literature?
8	controlled trial to get at the question of whether	8	A. So actually, in one of the papers that you
9	you needed to add capnography in as another means of	9	showed me from the GRADE chapters, they actually
10	monitoring to get even safer.	10	talk about it. But, yeah, I mean, it's an option.
11	Q. My question was perhaps simpler, which is,	11	You can include grey literature if that's
12	isn't it the case that it's well known that	12	appropriate for your question.
13	uncontrolled studies are at risk of serious bias as	13	Q. If you turn to well, turn the second
14	a result of effects such as confounding variables or	14	column on Page 2, towards the bottom is a heading
15	the placebo effect?	15	"Quality and potential bias." And there there's a
16	A. No, not necessarily.	16	reference to using a modified Jadad score, because
17	MS. LEVI: Object as to form.	17	we didn't have enough scores already.
18	THE WITNESS: Oh, sorry.	18	What is the Jadad score?
	-	19	A. You know, this was something that Roger
19	MS. LEVI: Just give me a second.	1/	
19 20	MS. LEVI: Just give me a second. Object as to form.	20	
	Object as to form.		Saunders actually introduced to me. But it was a
20	Object as to form. A. No, no. Not necessarily. In fact, there	20	Saunders actually introduced to me. But it was a way of looking at studies and deciding how they
20 21	Object as to form.	20 21	Saunders actually introduced to me. But it was a way of looking at studies and deciding how they you know, how to assess them. So it's just another
20 21 22	Object as to form. A. No, no. Not necessarily. In fact, there are all kinds of ways now of designing trials that	20 21 22	Saunders actually introduced to me. But it was a way of looking at studies and deciding how they

30 (Pages 114 - 117)

1	Page 118		Page 120
1	quote, "The Jadad score assesses studies based on	1	Do you know one way or the other?
2	their design (randomized and blinded) and their	2	A. I know nothing. All I'm thinking is that
3	reporting (all patients accounted for), with a	3	this is 1996. So we talked about my medical school
4	maximal score of 5 and a low score of 0."	4	graduation. This is as we're all trying to
5	Am I correct that the Jadad system rates	5	understand is it important or not.
6	more than simply whether it's randomized or blinded	6	Q. Right. Okay. Fair enough.
7	and whether all patients are accounted for? Those	7	It appears to describe the Jadad score
8	are just examples?	8	system that was referred to in your paper
9	A. I think the Jadad score is a very specific	9	A. Okay.
10	way of trying to assess a clinical trial design.	10	Q albeit introduced to you by one of your
11	Q. Okay. Why is it important, in clinical	11	co-authors, I think you testified. And as you say,
12	trial design, to know whether all patients are	12	in the introduction, this paper by Dr. Jadad,
13	accounted for in the experiment outcomes?	13	Exhibit 13, begins "The use of reliable data to
14	A. Sorry. Can you repeat that question.	14	support medical and public health decisions is
15	Q. Yes. I'm just referring to the	15	essential."
16	parentheses the parenthetical that says "all	16	And am I correct that you've been telling
17	patients accounted for." And my question is, why is	17	me that this was essentially a new focus of medicine
18	it important, in evaluating the strength of a study,	18	about the time you were graduating from medical
19	to know whether all patients are accounted for?	19	school?
20	A. Maybe I'm missing this. (Reviewing	20	A. Yes.
21	document) Oh, "and their reporting."	21	Q. Okay. If you turn to Page 11 you will
22	I mean, I think you would it may or may	22	see that we are now in the Appendix, which is
23	not be important. It's just again, the Jadad	23	"Instrument to Measure the Likelihood of Bias," and
24	score was a way of saying, "We're looking at a	1	
	Page 119		Page 121
1	series of studies, and how do we want to rate those	1	as you said, it's very narrow. It focuses on
2	studies?"	2	randomization, blinding and withdrawals and
3	And, you know, you can we did this big	3	dropouts.
3 4		3 4	dropouts. Let me ask you to read to yourself the
	literature search, you're going to come up with a		Let me ask you to read to yourself the
4	literature search, you're going to come up with a bunch of study, and then you want to be able to say,	4	
45	literature search, you're going to come up with a	4 5	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts.
4 5 6	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're	4 5 6 7	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study,
4 5 6 7	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very	4 5 6 7	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay.
4 5 6 7 8	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all	4 5 6 7 8	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study?
4 5 6 7 8 9	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together.	4 5 6 7 8 9	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of
4 5 6 7 8 9 10	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of	4 5 6 7 8 9 10	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form.
4 5 6 7 8 9 10 11	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all	4 5 6 7 8 9 10 11	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could
4 5 6 7 8 9 10 11 12	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So	4 5 6 7 8 9 10 11 12	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and
4 5 6 7 8 9 10 11 12 13	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more	4 5 6 7 8 9 10 11 12 13	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of
4 5 6 7 8 9 10 11 12 13 14	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more detail.	4 5 7 8 9 10 11 12 13 14	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself it's just another way to think about what
4 5 6 7 8 9 10 11 12 13 14 15	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more detail. MR. BROOKS: Let me ask the reporter to	4 5 6 7 8 9 10 11 12 13 14 15	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself it's just another way to think about what happened with the trial.
4 5 6 7 8 9 10 11 12 13 14 15 16	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more detail. MR. BROOKS: Let me ask the reporter to mark a paper "Assessing the Quality of Reports of	4 5 6 7 8 9 10 11 12 13 14 15 16	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself it's just another way to think about what happened with the trial. And in 1996 they said, "Gee, maybe we'd
4 5 6 7 8 9 10 11 12 13 14 15 16 17	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more detail. MR. BROOKS: Let me ask the reporter to mark a paper "Assessing the Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?"	4 5 6 7 8 9 10 11 12 13 14 15 16 17	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself it's just another way to think about what happened with the trial. And in 1996 they said, "Gee, maybe we'd better pay attention to is it a trial where, you
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more detail. MR. BROOKS: Let me ask the reporter to mark a paper "Assessing the Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Dr. Jadad and others from 1996.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself it's just another way to think about what happened with the trial. And in 1996 they said, "Gee, maybe we'd better pay attention to is it a trial where, you know, people withdrew, and have they explained
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more detail. MR. BROOKS: Let me ask the reporter to mark a paper "Assessing the Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Dr. Jadad and others from 1996. (Document marked as Lightdale	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself it's just another way to think about what happened with the trial. And in 1996 they said, "Gee, maybe we'd better pay attention to is it a trial where, you know, people withdrew, and have they explained that." And that would seem just logically
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more detail. MR. BROOKS: Let me ask the reporter to mark a paper "Assessing the Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Dr. Jadad and others from 1996. (Document marked as Lightdale Exhibit 13 for identification)	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself it's just another way to think about what happened with the trial. And in 1996 they said, "Gee, maybe we'd better pay attention to is it a trial where, you know, people withdrew, and have they explained that." And that would seem just logically important.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	literature search, you're going to come up with a bunch of study, and then you want to be able to say, you know, "80 percent of the studies scored very well on the Jadad score," or I mean, you're trying to decide how to think about those in all together. I mean, that reporting is saying one of the items in the Jadad score is just saying, are all patients accounted for in what they added up. So Q. Well, let me break out a little more detail. MR. BROOKS: Let me ask the reporter to mark a paper "Assessing the Quality of Reports of Randomized Clinical Trials: Is Blinding Necessary?" by Dr. Jadad and others from 1996. (Document marked as Lightdale Exhibit 13 for identification) Q. Dr. Lightdale, all I can say is this paper	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Let me ask you to read to yourself the paragraph relating to withdrawals and dropouts. A. (Reviewing document) Okay. Q. Why, in evaluating the strength of a study, is it important to know the number and reasons of those who did not complete the study? MS. LEVI: Object as to form. A. There can be a number of reasons. It could be interesting to understand withdrawals and dropouts. I don't think it's, you know, in and of itself it's just another way to think about what happened with the trial. And in 1996 they said, "Gee, maybe we'd better pay attention to is it a trial where, you know, people withdrew, and have they explained that." And that would seem just logically important. Q. Why?

31 (Pages 118 - 121)

	D (00		D 141
1	Page 122	1	Page 124
	a whole I mean, it's incredible, right? We were	1	don't do that, we don't understand what we got out
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	practicing medicine.	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	of the trial.
3	Q. You're really harsh on the medical field.	3	And so, again, that concept is brand-new in
4	But go ahead.	4	1996, you know.
5	A. It's true. It's how I was taught, you know. It's like nobody was saying, "Where's the	5	Q. Let me flip it, flip the hypothetical, and
6	evidence?" And now we're starting to say, "Oh,	6 7	let's drop it to 30 percent
8	maybe we need to notice this."	8	A. Okay.Q 30 percent who don't who just, over
9	So you can potentially have a trial where,		the course of the study, stopped coming back for
10	you know, the intervention leads everybody to, let's	9 10	maybe it's because it was a hassle, maybe it's
11	say, I don't know like, it's too much. That's a	11	because they benefited, maybe it's because it hurt
12	classic one that will happen, where it's just and	12	them. We don't know. We have no information on why
13	sometimes it's not the intervention. Sometimes it's	12	they dropped out.
14	the study itself was designed in a way that is so	13	One thing that could be the case is that
15	impossible for people to do: Come three times a	15	they have the treatment has made them feel really
16	week from, you know, wherever you are in order to do	16	sick, and they just don't feel like doing it
17	something.	17	anymore. They're upset, and they don't want to
18	People may simply not be able to do that	18	follow through.
19	for a sustained period of time. And that, alone,	19	In that case, if you looked only at the
20	can lead to lots of dropouts, never mind the	20	results for the 70 percent who kept coming, you
21	treatment itself.	21	might get an unduly optimistic reading on the effect
22	So I think understanding what is it, why	22	of the treatment; am I correct?
23	were there dropouts, why was there withdrawal is	23	MS. LEVI: Object as to form.
24	sort of now something we take for granted. But in	24	A. So once, in 1996, we started paying
-			
1	Page 123 1996 Dr. Jadad is saying, "Let's pay attention to	1	Page 125 attention to the fact that, "Oh, people withdraw or
2	this. This could be a piece of how to think about a	$\begin{vmatrix} 1\\2 \end{vmatrix}$	drop out of studies," we started coming up with
3	high quality study; not just did it happen, but did	$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	statistical approaches to what you do to avoid that
	someone explain to me why it happend."	4	
4	someone explain to me why it habbened		particular what you're bringing up concern
4 5			particular, what you're bringing up, concern. So certainly we want the investigators
5	Q. If you had and this is purely abstract.	5	So certainly we want the investigators
	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year	5 6	So certainly we want the investigators themselves to notice that 30 percent of their, you
5 6 7	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the		So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it.
5 6 7 8	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped	5 6 7 8	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like.
5 6 7 8 9	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically	5 6 7 8 9	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right
5 6 7 8 9 10	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50	5 6 7 8 9 10	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right.
5 6 7 8 9 10 11	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained.	5 6 7 8 9 10 11	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a
5 6 7 8 9 10	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that	5 6 7 8 9 10	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper.
5 6 7 8 9 10 11 12	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained.	5 6 7 8 9 10 11 12	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a
5 6 7 8 9 10 11 12 13	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so	5 6 7 8 9 10 11 12 13	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that
5 6 7 8 9 10 11 12 13 14	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment	5 6 7 8 9 10 11 12 13 14	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat
5 6 7 8 9 10 11 12 13 14 15	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on	5 6 7 8 9 10 11 12 13 14 15	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat methodologies where you're going to basically, if
5 6 7 8 9 10 11 12 13 14 15 16	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on those who continued coming, you would get an	5 6 7 8 9 10 11 12 13 14 15 16	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat methodologies where you're going to basically, if someone doesn't finish, that actually will go
5 6 7 8 9 10 11 12 13 14 15 16 17	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on those who continued coming, you would get an inaccurately negative understanding of the effect of	5 6 7 8 9 10 11 12 13 14 15 16 17	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat methodologies where you're going to basically, if someone doesn't finish, that actually will go against the study finding. So you're designing a
5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on those who continued coming, you would get an inaccurately negative understanding of the effect of the treatment, correct?	5 6 7 8 9 10 11 12 13 14 15 16 17 18	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat methodologies where you're going to basically, if someone doesn't finish, that actually will go against the study finding. So you're designing a study and weighing it in a way that you're being
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on those who continued coming, you would get an inaccurately negative understanding of the effect of the treatment, correct? MS. LEVI: Object as to form.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat methodologies where you're going to basically, if someone doesn't finish, that actually will go against the study finding. So you're designing a study and weighing it in a way that you're being very conservative.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on those who continued coming, you would get an inaccurately negative understanding of the effect of the treatment, correct? MS. LEVI: Object as to form. A. I mean I don't know. I think that it's 	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat methodologies where you're going to basically, if someone doesn't finish, that actually will go against the study finding. So you're designing a study and weighing it in a way that you're being very conservative. And so now I'm looking to understand, was
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on those who continued coming, you would get an inaccurately negative understanding of the effect of the treatment, correct? MS. LEVI: Object as to form. A. I mean I don't know. I think that it's very it's so hypothetical. 	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat methodologies where you're going to basically, if someone doesn't finish, that actually will go against the study finding. So you're designing a study and weighing it in a way that you're being very conservative. And so now I'm looking to understand, was it an intention-to-treat methodology, were there
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. If you had and this is purely abstract. If you had a study let's say it's a two-year study; it's going to go on for a while and by the end, 50 percent of the participants have dropped out; they just haven't showed up. Hypothetically and you just looked at the results for the 50 percent who remained. Now, one possible explanation would be that the 50 percent who stopped coming had benefited so much they just didn't feel the need of treatment anymore. And in that case, if you focused only on those who continued coming, you would get an inaccurately negative understanding of the effect of the treatment, correct? MS. LEVI: Object as to form. A. I mean I don't know. I think that it's very it's so hypothetical. So I think what's important is to notice 	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	So certainly we want the investigators themselves to notice that 30 percent of their, you know, population didn't finish the study and say it. I'm saying "We," by the way, very grandiose like. But this is what you're looking for, right Q. Right. A when you're trying to understand a paper. But actually there are methodologies that you use they call them intention-to-treat methodologies where you're going to basically, if someone doesn't finish, that actually will go against the study finding. So you're designing a study and weighing it in a way that you're being very conservative. And so now I'm looking to understand, was it an intention-to-treat methodology, were there other statistical ways that somebody tried to

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 34 of 58

CONFIDENTIAL

	Page 126		Page 128
1	And I think these days we design trials	1	study, but it's an extremely small sample, correct?
2	knowing not everybody is going to finish. So you	2	A. Yes.
3	have to say, a priori, what you are going to do to	3	Q. And your goal, it says, down in "Objective"
4	make sure that you don't bias your own study by	4	a little farther in the abstract, is to apply the
5	being left with your 70 percent.	5	scientific method to assess the reproducibility of
6	Q. Okay.	6	those reported effects, correct?
7	MS. LEVI: We're close to noon. I'm not	7	A. Yes.
8	asking for a lunch break, but it would be good to	8	Q. And can you explain to me the distinction
9	take another break.	9	between the scientific method that you're referring
10	MR. BROOKS: Yeah. And my recommendation	10	to here and obviously you've described earlier
11	would be we take a break, we do one more run,	11	there's been a published paper describing these
12	because stopping at noon always makes the afternoon	12	three children's experiences.
13	rough.	13	What's the difference between that paper
14	MS. LEVI: Yeah.	14	that existed and the scientific method that you
15	MR. BROOKS: So, yeah. Now is a fine time	15	referred to under "Objective"?
16	to stop.	16	A. Can I take a look at it? I haven't seen it
17	(Recess)	17	in a long time.
18	MR. BROOKS: Let me ask the reporter to	18	Q. Of course you may.
19	mark as Lightdale Exhibit 14 a paper from 2001	19	A. (Reviewing document) Okay. Because I did
20	titled "Effects of Intravenous Secretin on Language	20	not remember that that was my objective. But I am
21	and Behavior of Children with Autism."	21	now, why did we phrase it that way?
22	(Document marked as Lightdale	22	What was your question?
23	Exhibit 14 for identification)	23	Q. Again, the beginning of the abstract, and I
24	Q. And, Dr. Lightdale, is this a paper on	24	didn't read it all, but it points out that this case
			•
	Page 127	1	Page 129
1	Page 127 which you were the first author?	1	Page 129 study of three autistic children was based on
1 2	Page 127 which you were the first author? A. Yes.	1 2 3	Page 129 study of three autistic children was based on reports from their parents over a five-week period,
1 2 3	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard	3	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right?
1 2 3 4	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work?	3 4	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my
1 2 3 4 5	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes.	3 4 5	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So
1 2 3 4 5 6	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about	3 4 5 6	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine.
1 2 3 4 5 6	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So	3 4 5 6 7	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand.
1 2 3 4 5 6 7 8	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood	3 4 5 6 7 8	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he
1 2 3 4 5 6 7 8 9	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly.	3 4 5 6 7 8 9	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said,
1 2 3 4 5 6 7 8 9 10	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time,	3 4 5 6 7 8 9 10	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay."
1 2 3 4 5 6 7 8 9 10 11	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous	3 4 5 6 7 8 9 10 11	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at
1 2 3 4 5 6 7 8 9 10 11 12	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic	3 4 5 6 7 8 9 10 11 12	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the
1 2 3 4 5 6 7 8 9 10 11 12 13	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct?	3 4 5 6 7 8 9 10 11 12 13	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized
1 2 3 4 5 6 7 8 9 10 11 12 13 14	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning	3 4 5 6 7 8 9 10 11 12 13 14 15	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped.
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning of the abstract, was due to simply a three a	3 4 5 6 7 8 9 10 11 12 13 14 15 16	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped. And we said, "Well, what do we do now?",
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning of the abstract, was due to simply a three a paper that described the experience of three	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped. And we said, "Well, what do we do now?", because we were in the middle of our design. And we
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\end{array} $	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning of the abstract, was due to simply a three a paper that described the experience of three children correct?	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped. And we said, "Well, what do we do now?", because we were in the middle of our design. And we decided that you could say that what we were doing
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning of the abstract, was due to simply a three a paper that described the experience of three children correct? A. Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped. And we said, "Well, what do we do now?", because we were in the middle of our design. And we decided that you could say that what we were doing was still important because of the scientific
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\end{array} $	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning of the abstract, was due to simply a three a paper that described the experience of three children correct? A. Yes. Q and parental reports specifically about	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped. And we said, "Well, what do we do now?", because we were in the middle of our design. And we decided that you could say that what we were doing was still important because of the scientific method, which means that you really ought to be
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning of the abstract, was due to simply a three a paper that described the experience of three children correct? A. Yes. Q and parental reports specifically about the supposed effect of intravenous secretin on the	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped. And we said, "Well, what do we do now?", because we were in the middle of our design. And we decided that you could say that what we were doing was still important because of the scientific method, which means that you really ought to be careful before you move to a randomized controlled
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\end{array} $	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning of the abstract, was due to simply a three a paper that described the experience of three children correct? A. Yes. Q and parental reports specifically about the supposed effect of intravenous secretin on the language skills of those three children.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped. And we said, "Well, what do we do now?", because we were in the middle of our design. And we decided that you could say that what we were doing was still important because of the scientific method, which means that you really ought to be careful before you move to a randomized controlled trial. You need to perform first an open-label
$ \begin{array}{c} 1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	Page 127 which you were the first author? A. Yes. Q. Indicating that you did most of the hard work? A. Yes. Q. All right. I have a few questions about it, but we kind of need to break out what it is. So let me see if I, after reading it, understood correctly. The background situation was, at the time, a widespread belief among parents that intravenous secretin improved language skills in autistic children, correct? A. Yes. Q. And that, according to the very beginning of the abstract, was due to simply a three a paper that described the experience of three children correct? A. Yes. Q and parental reports specifically about the supposed effect of intravenous secretin on the	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Page 129 study of three autistic children was based on reports from their parents over a five-week period, right? A. This was an extraordinary moment in my life, but I will tell you, I was very junior. So the senior author is a long-time mentor of mine. Q. I understand. A. I was just getting interested in GI, and he said, "I have a study for you to do," and I said, "Okay." And while we were trying to get it going at UCSF, other groups, in particular a group at the University of North Carolina, published a randomized controlled trial. So the sense was that we had been scooped. And we said, "Well, what do we do now?", because we were in the middle of our design. And we decided that you could say that what we were doing was still important because of the scientific method, which means that you really ought to be careful before you move to a randomized controlled

33 (Pages 126 - 129)

	Page 130		Page 132
1	So the open-label design, smaller study,	1	But I can answer the question of why
2	open label, allowed us to do a whole lot of	2	prospective data can be important in a moment like
3	different measures on these kids that you could not	3	this.
4	do in a randomized controlled trial, which is bigger	4	Q. All right.
5	and wasn't based on it didn't have even the right	5	A. So, without a doubt, retrospective data is
6	data to even do a sample size determination, is my	6	going to be limited in different ways, because you
7	memory.	7	can you can only look at what was reported.
8	So, you know, we felt that they had moved	8	And, of course, if the retrospective data
9	too quickly to the randomized controlled trial, and	9	involves, you know, basically, in this case, parents
10	we could make the argument that our study was still	10	describing that things have changed, there wasn't
11	important.	11	necessarily good data captured on the baseline
12	Q. So let me focus on one thing you just	12	before something happened. So all we're getting is,
13	mentioned.	13	after the fact, somebody saying, "Oh, something has
14	If you turn to Page 2, the top of the	14	changed."
15	second column is a paragraph that begins, "To	15	Prospectively we could really measure the
16	formally answer these questions, it seems necessary	16	kids at their baseline, and then we could give them
17	to observe the basic principles of scientific method	17	the secretin, and then we could say, "Did something
18	by prospectively investigating the reproducibility	18	change?"
19	of the reported effects," correct?	19	Q. Okay. And looking at that, let's turn to
20	A. Yes.	20	Page 3. There's a section headed "Measures," and
21	Q. And what were you referring to as "the	21	there you state that "Children's language level was
22	basic principles of scientific method"?	22	assessed using the PLS-3."
23	A. So I don't actually quite remember	23	Is that a well-recognized, objective
24	exactly, but I think the scientific method would	24	measure of language skills?
	Page 131		Page 133
1	Page 131 state that you need to really be clear what your	1	Page 133 A. So I had a number of people involved in
1	state that you need to really be clear what your	1	A. So I had a number of people involved in
1 2 3	state that you need to really be clear what your question is, and then you need to decide if you're	2	A. So I had a number of people involved in this study, and a couple of them were experts in
3	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it.	2 3	A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and
34	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should	2 3 4	A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the
3 4 5	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was	2 3 4 5	A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way.
3 4 5 6	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting	2 3 4 5 6	A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way.Q. Do you know whether PLS-3 was a
3 4 5 6 7	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more	2 3 4 5 6 7	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language
3 4 5 6 7 8	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this.	2 3 4 5 6 7 8	A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills?
3 4 5 6 7 8 9	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with	2 3 4 5 6 7 8 9	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale.
3 4 5 6 7 8 9 10	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else	2 3 4 5 6 7 8 9 10	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you
3 4 5 6 7 8 9 10 11	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate	2 3 4 5 6 7 8 9 10 11	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language
3 4 5 6 7 8 9 10 11 12	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So	2 3 4 5 6 7 8 9 10 11 12	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills?
3 4 5 6 7 8 9 10 11 12 13	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said	2 3 4 5 6 7 8 9 10 11 12 13	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was
3 4 5 6 7 8 9 10 11 12 13 14	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of	2 3 4 5 6 7 8 9 10 11 12 13 14	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the
3 4 5 6 7 8 9 10 11 12 13 14 15	state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating."	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed.
3 4 5 6 7 8 9 10 11 12 13 14 15 16	 state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating." A. Uh-huh. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed. Q. And it did not, am I correct, depend on
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating." A. Uh-huh. Q. Why was it important why do you consider 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed. Q. And it did not, am I correct, depend on parental reports?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating." A. Uh-huh. Q. Why was it important why do you consider that prospective investigation rather than, for 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed. Q. And it did not, am I correct, depend on parental reports? A. Yeah, it's basically it's a very I
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating." A. Uh-huh. Q. Why was it important why do you consider that prospective investigation rather than, for instance, a retrospective analysis is among the 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed. Q. And it did not, am I correct, depend on parental reports? A. Yeah, it's basically it's a very I don't really again, I was not the person
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating." A. Uh-huh. Q. Why was it important why do you consider that prospective investigation rather than, for instance, a retrospective analysis is among the basic principles of the scientific method? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed. Q. And it did not, am I correct, depend on parental reports? A. Yeah, it's basically it's a very I don't really again, I was not the person administering these particular scales. But
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating." A. Uh-huh. Q. Why was it important why do you consider that prospective investigation rather than, for instance, a retrospective analysis is among the basic principles of the scientific method? A. It's funny, because I am not sure I can 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed. Q. And it did not, am I correct, depend on parental reports? A. Yeah, it's basically it's a very I don't really again, I was not the person administering these particular scales. But basically, they were you know, we were going to
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating." A. Uh-huh. Q. Why was it important why do you consider that prospective investigation rather than, for instance, a retrospective analysis is among the basic principles of the scientific method? A. It's funny, because I am not sure I can tell you exactly what the scientific method is 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed. Q. And it did not, am I correct, depend on parental reports? A. Yeah, it's basically it's a very I don't really again, I was not the person administering these particular scales. But basically, they were you know, we were going to do a number of different measures, and one of them
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 state that you need to really be clear what your question is, and then you need to decide if you're measuring what you need to to answer it. And I think we decided that we still should be doing this open-label trial, because this was actually going to either be helpful for supporting or refuting, you know, moving forward and doing more studies with this. So, again, I think we had to come up with an objective that met the moment of somebody else publishing a trial that almost seemed to obviate what we had done. So Q. In the same sentence I've read, you said you needed "to observe the basic principles of scientific method by prospectively investigating." A. Uh-huh. Q. Why was it important why do you consider that prospective investigation rather than, for instance, a retrospective analysis is among the basic principles of the scientific method? A. It's funny, because I am not sure I can 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. So I had a number of people involved in this study, and a couple of them were experts in measuring developmental behavioral pediatrics and language and things like that. So they were the ones that came up with the measures that way. Q. Do you know whether PLS-3 was a pre-existing objective measurement of language skills? A. My understanding is it's a validated scale. Q. Dated or outdated, my question was, did you understand it to be an objective measure of language skills? A. I think we picked a measure we thought was going to be a good measure for understanding if the language skills changed. Q. And it did not, am I correct, depend on parental reports? A. Yeah, it's basically it's a very I don't really again, I was not the person administering these particular scales. But basically, they were you know, we were going to

34 (Pages 130 - 133)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 36 of 58

CONFIDENTIAL

	Page 134		Page 136
1	3, it says, in the first full paragraph, "Language	1	A. Yes.
2	and behavioral measures were repeated at T2 to T5."	2	Q. And I'm sorry, I've taken things out of
3	A. Where are you now?	3	order. If you back up to the bottom of the second
4	Q. It's the first full paragraph at the top of	4	column on Page 3, it states, "Analyses revealed no
5	Column 2 of Page 3.	5	significant increases in children's language skills
6	A. Oh, I see. Okay.	6	from baseline following a single infusion of
7	Q. And noticing the word "repeated," am I	7	secretin," correct?
8	correct that part of your protocol was that you did	8	A. Yes.
9	this objective test of language skills at each of	9	Q. Do you recall, at least, that the big
10	T1, T2, T3, T4, T5?	10	picture take-away from this paper was that secretin
11	MS. LEVI: Object as to form.	11	did not improve children's language skills and
12	A. Yeah, so, in full disclosure, I haven't	12	parents thought it did?
13	really thought about this study in a very long time.	13	MS. LEVI: Object as to form.
14	So I don't quite remember the whole bits to it. I	14	A. My own when I tell the story of this
15	more remember what was going on around it.	15	paper, the big take-away was secretin did nothing.
16	But so I would have to honestly get into	16	Q. But am I correct that another important
17	this a little bit.	17	take-away was, notwithstanding it did nothing, that
18	Q. Well, let me ask about	18	many parents thought it was having a beneficial
19	A. I mean, I can read it if you want	19	effect on their children?
20	Q. No. Let me ask	20	MS. LEVI: Object as to form.
21	A to see what I wrote.	21	A. The answer for me is, I didn't remember
22	Q. Let me ask some big picture questions and	22	that piece of it, but it is there.
23	see if you recall at the big picture level.	23	Q. Okay. If you turn to Page 5, Column 1,
24	A. Yes.	24	about an inch from the top, a sentence begins, "This
	Page 135		Page 137
			1 4 60 10 7
1	Q. If you turn to Page 4	1	pattern of parental response." Do you see that?
1 2	Q. If you turn to Page 4MS. LEVI: If you want to take time to	1 2	-
	MS. LEVI: If you want to take time to review your study		pattern of parental response." Do you see that?A. Uh-huh.Q. It reads, "This pattern of parental
2	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true.	2	pattern of parental response." Do you see that?A. Uh-huh.Q. It reads, "This pattern of parental response is consistent with previously published
23	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free	2 3	pattern of parental response." Do you see that?A. Uh-huh.Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for
2 3 4	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see	2 3 4	pattern of parental response." Do you see that?A. Uh-huh.Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative
2 3 4 5 6 7	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need.	2 3 4 5	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or
2 3 4 5 6	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like,	2 3 4 5 6 7 8	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence."
2 3 4 5 6 7 8 9	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very	2 3 4 5 6 7 8 9	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based
2 3 4 5 6 7 8 9 10	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level,	2 3 4 5 6 7 8 9 10	pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional
2 3 4 5 6 7 8 9 10 11	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read.	2 3 4 5 6 7 8 9 10 11	pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or,
2 3 4 5 6 7 8 9 10 11 12	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good.	2 3 4 5 6 7 8 9 10 11 12	pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be
2 3 4 5 6 7 8 9 10 11 12 13	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as	2 3 4 5 6 7 8 9 10 11 12 13	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate?
2 3 4 5 6 7 8 9 10 11 12 13 14	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says,	2 3 4 5 6 7 8 9 10 11 12 13 14	pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is known that any self-report is always going to be
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was found between parental reports of change and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is known that any self-report is always going to be suspect. And certainly when parents are being
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was found between parental reports of change and observable improvement in the sample."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is known that any self-report is always going to be suspect. And certainly when parents are being asked, there's this added level of, well, we don't
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was found between parental reports of change and observable improvement in the sample." Do you see that?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is known that any self-report is always going to be suspect. And certainly when parents are being asked, there's this added level of, well, we don't know what it means.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was found between parental reports of change and observable improvement in the sample." Do you see that? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is known that any self-report is always going to be suspect. And certainly when parents are being asked, there's this added level of, well, we don't know what it means. So you have to take, you know, basically
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was found between parental reports of change and observable improvement in the sample." Do you see that? A. Yes. Q. And it says goes on to say that "70 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is known that any self-report is always going to be suspect. And certainly when parents are being asked, there's this added level of, well, we don't know what it means. So you have to take, you know, basically reported self-reports and then parental reports
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was found between parental reports of change and observable improvement in the sample." Do you see that? A. Yes. Q. And it says goes on to say that "70 percent" of parents "reported moderate to high 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is known that any self-report is always going to be suspect. And certainly when parents are being asked, there's this added level of, well, we don't know what it means. So you have to take, you know, basically reported self-reports and then parental reports of children's behavior just have to be held as a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 MS. LEVI: If you want to take time to review your study MR. BROOKS: That's certainly true. MS. LEVI: you should feel free THE WITNESS: It's weird to see MS. LEVI to take the time you need. THE WITNESS: my own words. It's, like, very, very Q. I'm going to try back up to the high level, and then you decide what you want to read. A. Okay. Sounds good. Q. If you turn to Page 4, Column 1, we are, as you'll see, in the "Results" section. It says, about an inch and a half from the bottom of the text from the first column, quote, "No relationship was found between parental reports of change and observable improvement in the sample." Do you see that? A. Yes. Q. And it says goes on to say that "70 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	pattern of parental response." Do you see that? A. Uh-huh. Q. It reads, "This pattern of parental response is consistent with previously published observations by others, and underscores the need for carefully designed trials of any putative therapeutic agent suggested by empirical or anecdotal evidence." So I want to ask a general question, based on your studies, based on your professional experience. Is it well known that self-reports or, in the case of children, parental reports can be highly inaccurate? MS. LEVI: Object as to form. A. Well, what I'll say is that I think it is known that any self-report is always going to be suspect. And certainly when parents are being asked, there's this added level of, well, we don't know what it means. So you have to take, you know, basically reported self-reports and then parental reports

35 (Pages 134 - 137)

	Page 138		Page 140
1	line this was an extraordinary moment going on,	1	Appendix A on Page S247, two inches down on the
2	but there was a hysteria. And so we knew that part	2	first column, it says, "The process for development
3	of what was happening is parents at that point were	3	of the SOC-8" let me see if you find that.
4	not thinking it was a single infusion; they were now	4	A. Okay.
5	wanting multiple infusions.	5	Q. "The process for development of the SOC-8
6	So, you know, these are strong emotions	6	incorporated recommendations on clinical practice
7	people are having, and they're ready to say things,	7	guideline development from the National Academies of
8	you know.	8	Medicine and The World Health Organization that
9	Q. Well, are there	9	addressed transparency, the conflict-of-interest
10	A. And it just I think what we were saying	10	policy, committee composition and group process,"
11	is, "You have to do this well." If we're going to	11	and it then cites a document from the Institute of
12	start talking about cures for autism, they have to	12	Medicine and from The World Health Organization.
13	be designed very well.	13	Do you see that?
14	Q. Are there recognized reasons why	14	A. Yes.
15	self-reports and parental reports are commonly	15	Q. Are you, yourself, familiar with a document
16	unreliable?	16	from the National Academies of Medicine or the
17	MS. LEVI: Object as to form.	17	Institute of Medicine that sets out procedures for
18	A. I mean, I think it's human nature not to be	18	developing guidelines?
19	able to objectively think about things. I mean,	19	A. I am familiar with it. It's a big
20	it's part of being human.	20	document. It's a book.
21	So, you know, anybody makes a big I	21	Q. Have you, yourself, consulted that such
22	don't know in this case says, "We've got a cure	22	a document from the Institute of Medicine?
23	for autism," based, you know, on self-reports only,	23	A. Yeah.
24	that would not be sufficient to move forward.	24	MR. BROOKS: Let me ask the reporter to
	Page 139		Page 141
1	And I think at this point we were	1	mark as Exhibit 15 a document published by the
2	contributing at this point to a body of evidence,	2	Institute of Medicine entitled "Clinical Practice
3	saying, "This is not a cure for autism, this	3	Guidelines We Can Trust." And I believe that this
4	secretin."	4	is selected chapters of, as you say, a whole book.
5	Q. And is the end of the story a broad medical	5	(Document marked as Lightdale
6	conclusion that secretin did not help?	6	Exhibit 15 for identification)
7	A. Yes.	7	Q. Let me ask you to take a look at this. And
8	MS. LEVI: Object as to form.	8	recognizing it is the cover page, the table of
9	THE WITNESS: Sorry.	9	contents and then selected chapters, does this
10	MS. LEVI: Make sure you give me a	10	appear to be portions of the book that you have in
11	chance	11	mind?
12	THE WITNESS: Apologies. I'm working on	12	A. Yes.
		13	Q. And you've cited this yourself, have you
13			
	Q. When you referred to, quote, "underscoring	14	not?
13	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any	15	A. Yes.
13 14	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal	15 16	A. Yes.Q. And is this a widely respected set of
13 14 15	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal evidence" let me start again. Pardon me. I'll	15 16 17	A. Yes.Q. And is this a widely respected set of criteria for good practices for developing
13 14 15 16 17 18	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal evidence" let me start again. Pardon me. I'll skip over that. It's too hard to package.	15 16 17 18	A. Yes.Q. And is this a widely respected set of criteria for good practices for developing guidelines?
13 14 15 16 17	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal evidence" let me start again. Pardon me. I'll skip over that. It's too hard to package. I have put back in order your exhibits, and	15 16 17 18 19	A. Yes.Q. And is this a widely respected set of criteria for good practices for developing guidelines?A. I think it's an important text in the
13 14 15 16 17 18	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal evidence" let me start again. Pardon me. I'll skip over that. It's too hard to package. I have put back in order your exhibits, and I'm going to ask you to find Exhibit 5 again, which	15 16 17 18 19 20	A. Yes.Q. And is this a widely respected set of criteria for good practices for developing guidelines?A. I think it's an important text in the field, yeah.
13 14 15 16 17 18 19	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal evidence" let me start again. Pardon me. I'll skip over that. It's too hard to package. I have put back in order your exhibits, and I'm going to ask you to find Exhibit 5 again, which is you can check me on this the methodology	15 16 17 18 19 20 21	 A. Yes. Q. And is this a widely respected set of criteria for good practices for developing guidelines? A. I think it's an important text in the field, yeah. Q. Is there any other that you consider to be
13 14 15 16 17 18 19 20	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal evidence" let me start again. Pardon me. I'll skip over that. It's too hard to package. I have put back in order your exhibits, and I'm going to ask you to find Exhibit 5 again, which is you can check me on this the methodology appendix to SOC-8. Sorry. We've got all sorts of	15 16 17 18 19 20 21 22	 A. Yes. Q. And is this a widely respected set of criteria for good practices for developing guidelines? A. I think it's an important text in the field, yeah. Q. Is there any other that you consider to be more authoritative in terms of good practice for
13 14 15 16 17 18 19 20 21	Q. When you referred to, quote, "underscoring the need for carefully designed trials of any therapeutic agent suggested by anecdotal evidence" let me start again. Pardon me. I'll skip over that. It's too hard to package. I have put back in order your exhibits, and I'm going to ask you to find Exhibit 5 again, which is you can check me on this the methodology	15 16 17 18 19 20 21	 A. Yes. Q. And is this a widely respected set of criteria for good practices for developing guidelines? A. I think it's an important text in the field, yeah. Q. Is there any other that you consider to be

36 (Pages 138 - 141)

	Page 142		Page 144
1		1	that I can
2	you really have in fact, you've brought it out.	2	Q. Here you are. You're an expert, here to
3	We have AGREE II which comes out much later.	3	offer opinions.
4	So at that time, in 2011, it was really	4	A. I'm the expert, okay.
5	helpful that they created this text that you could	5	So I think we're all learning, still, as we
6	reference.	6	go. And so the transparency gets important, because
7	Q. Do you know whether the Institute of	7	I need to understand, as a, you know, physician or
8	Medicine has publish any more updated version of	8	somebody who's going to potentially going to use a
9	this?	9	guideline, how did it happen?
10	A. I don't think so.	10	And actually in some ways it goes along
11	Q. And we've seen together that this was cited	11	with like, I think we've talked a little bit
12	in the SOC-8 methodology, correct?	12	about this, but there was that discussion how AGREE
13	A. Yes.	13	II starts talking about the funding source, right?
14	Q. Do you believe that accepted good practice	14	So we need to understand who is driving the
15	for developing guidelines has become, shall I say,	15	guideline, why is it happening, how did they do it.
16	tighter, more rigorous since 2011?	16	And so that transparency has actually
17	A. Yes.	17	become really important. And it's been a piece of
18	Q. Not less?	18	evolving and, again, something we're continuously
19	A. Become tighter. Yes.	19	improving. I don't think anything's done yet. I
20	Q. In your report, which we've marked as	20	bet there's an AGREE III in a couple of years.
21	Exhibit 4, you wrote, in Paragraph 19 on Page 6,	21	So, you know, it's just, like it's
22	quote, "WPATH's process for developing SOC-8, as	22	constantly trying to get guidelines better. Is that
23	described at," and then you have the you have a	23	okay?
24	live link, actually, to the web page in question,	24	Q. Let me ask you to find that Institute of
	D 110		
	Page 143		Page 145
1	right? "is transparent, rigorous, and	1	Page 145 Medicine document again, Exhibit 14 (sic), and I
1 2	-	1 2	
	right? "is transparent, rigorous, and		Medicine document again, Exhibit 14 (sic), and I
2	right? "is transparent, rigorous, and methodologically sound."	2	Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42.
23	right? "is transparent, rigorous, and methodologically sound." Do you see that language?	2 3	Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on.
2 3 4	right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes.	2 3 4	Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating).
2 3 4 5	right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in	2 3 4 5	Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42.A. Hold on.MS. LEVI: I think it's this (indicating).Q. This is what it looks like (indicating).
2 3 4 5 6	right? "is transparent, rigorous, and methodologically sound." Do you see that language?A. Yes.Q. And you were referring to what you read in that web page, not to any actual knowledge of what	2 3 4 5 6	Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42.A. Hold on.MS. LEVI: I think it's this (indicating).Q. This is what it looks like (indicating).A. Sorry. This one.
2 3 4 5 6 7	right? "is transparent, rigorous, and methodologically sound." Do you see that language?A. Yes.Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct?	2 3 4 5 6 7	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42.
2 3 4 5 6 7 8	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. 	2 3 4 5 6 7 8	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the
2 3 4 5 6 7 8 9	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent 	2 3 4 5 6 7 8 9	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the
2 3 4 5 6 7 8 9 10	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and 	2 3 4 5 6 7 8 9 10	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the
2 3 4 5 6 7 8 9 10 11	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. 	2 3 4 5 6 7 8 9 10 11	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health?
2 3 4 5 6 7 8 9 10 11 12	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and 	2 3 4 5 6 7 8 9 10 11 12	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Association of National Academy
2 3 4 5 6 7 8 9 10 11 12 13	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the 	2 3 4 5 6 7 8 9 10 11 12 13	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Association of National Academy of Sciences.
2 3 4 5 6 7 8 9 10 11 12 13 14	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is 	2 3 4 5 6 7 8 9 10 11 12 13 14	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Association of National Academy of Sciences. Q. National Academy
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is in multiple different layers. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Academy A of Sciences.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is in multiple different layers. So you want to, I think in a very 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Academy A of Sciences. Q. Is it governmental entity?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is in multiple different layers. So you want to, I think in a very general way, the most important transparent thing is 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Academy A of Sciences. Q. Is it governmental entity? A. It is not, technically. It's, like it
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is in multiple different layers. So you want to, I think in a very general way, the most important transparent thing is to say how you you know, what you were looking to 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Academy A of Sciences. Q. Is it governmental entity? A. It is not, technically. It's, like it is and it's not. So or I don't know. I don't
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is in multiple different layers. So you want to, I think in a very general way, the most important transparent thing is to say how you you know, what you were looking to do and how you did it. And then, from there, 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Association of National Academy of Sciences. Q. Is it governmental entity? A. It is not, technically. It's, like it is and it's not. So or I don't know. I don't actually and I'm not in it is the truth.
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\end{array} $	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is in multiple different layers. So you want to, I think in a very general way, the most important transparent thing is to say how you you know, what you were looking to do and how you did it. And then, from there, transparency plays out in lots of other ways. So 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Academy A of Sciences. Q. Is it governmental entity? A. It is not, technically. It's, like it is and it's not. So or I don't know. I don't actually and I'm not in it is the truth. Q. Let's not spend time parsing out it is and
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	 right? "is transparent, rigorous, and methodologically sound." Do you see that language? A. Yes. Q. And you were referring to what you read in that web page, not to any actual knowledge of what the WPATH team did, correct? A. Right. Q. And you said the process was transparent and rigorous. Can you explain to me the meaning and importance of transparency in guideline development. A. So I think to be transparent and methodologically rigorous, as AGREE II says, is the goal these days of guidelines, and transparency is in multiple different layers. So you want to, I think in a very general way, the most important transparent thing is to say how you you know, what you were looking to do and how you did it. And then, from there, transparency plays out in lots of other ways. So 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Medicine document again, Exhibit 14 (sic), and I want to ask you to turn in there to Page 42. A. Hold on. MS. LEVI: I think it's this (indicating). Q. This is what it looks like (indicating). A. Sorry. This one. Q. And if you would turn to 42. And just for clarity, we referred to the Institute of Medicine. Am I correct that the Institute of Medicine is also or now known as the National Institutes of Health? A. National Association of National Academy of Sciences. Q. Is it governmental entity? A. It is not, technically. It's, like it is and it's not.

37 (Pages 142 - 145)

	Page 146		Page 148
1	government commissions it.	1	produce clinical guidance."
2	Q. Okay.	2	Were you aware, before reading that, that
3	42 begins, "Organizations in several	3	NICE conducts or contracts for systematic reviews?
4	countries outside the U.S. also produce clinical	4	A. What I I didn't know that specifically.
5	practice guidelines."	5	What I knew
6	And it goes in the next paragraph it	6	MS. LEVI: That was the question.
7	begins, "For example, the National Institute for	7	Q. That was the question.
8	Health and Clinical Excellence (NICE) is an	8	A. Okay.
9	independent organization that advises the UK	9	Q. So you don't have any view as to the
10	National Health Service," and it continues.	10	reputation of NICE for performing thorough or
11	Are you familiar with the reputation of the	11	reliable systematic reviews?
12	UK NICE?	12	A. No.
13	A. I know what the NICE is.	13	Q. Okay.
14	Q. Is it a respected source of analysis of	14	Do you agree that transparency in the
15	medical science?	15	development of a appropriate transparency in
16	MS. LEVI: Object as to form.	16	connection with a clinical practice guideline
17	A. Respected by who, I guess? Like, by	17	includes disclosure of the design of any systematic
18	Americans? We don't necessarily follow NICE stuff.	18	searches that were done, for instance, the PICO
19	Q. Well, what does NICE do, to your knowledge?	19	criteria?
20	A. Okay. So this is purely what I understand.	20	MS. LEVI: Object as to form.
21	Q. That's all you can ever testify to.	21	A. Actually I apologize, because I am
22	A. But the UK, unlike the United States, in	22	getting a little tired. So can you repeat that
23	around actually, around as I'm graduating from	23	question?
24	medical school, forms the National Health Service	24	MS. LEVI: Do you need a break?
	Page 147		Page 149
1	and puts in place, over time, this National	1	THE WITNESS: Maybe. Maybe.
2	Institute for Health and Clinical Excellence, the	2	MS. LEVI: It's perfectly fine.
3	NICE, which basically that's what I call it	3	MR. BROOKS: We can break for lunch now.
4	which basically comes up with standards of care and	4	MS. LEVI: Okay. Why don't we do that.
5	guidelines that go across the UK.	5	MR. BROOKS: Fine.
6	Unfortunately, the United States didn't	6	THE WITNESS: Is that okay?
17	have that. So we have had a system that hasn't had	7	MS. LEVI: Of course. Absolutely. You get
8	single payer like the National Health Service, and	8	to absolutely.
9	instead we have allowed guidelines or we've	9	THE WITNESS: Okay. 12:40. I might have
10	actually basically made it in the United States that	10	hit my, like, lunchtime.
1.4.4			-
11	if you're going to have guidelines, it's all these	11	MR. BROOKS: That is just fine.
12	if you're going to have guidelines, it's all these independent groups that have to create them.	12	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for
12 13	if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not	12 13	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour?
12 13 14	if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single	12 13 14	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.
12 13 14 15	if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We	12 13 14 15	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour?
12 13 14 15 16	if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its	12 13 14 15 16	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.
12 13 14 15 16 17	if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its guidelines, WPATH doing its guidelines. I mean,	12 13 14 15 16 17	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.
12 13 14 15 16 17 18	if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its guidelines, WPATH doing its guidelines. I mean, everybody is doing their own guidelines. So	12 13 14 15 16 17 18	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.
12 13 14 15 16 17 18 19	 if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its guidelines, WPATH doing its guidelines. I mean, everybody is doing their own guidelines. So Q. The next sentence in this second full 	12 13 14 15 16 17 18 19	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.
12 13 14 15 16 17 18 19 20	 if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its guidelines, WPATH doing its guidelines. I mean, everybody is doing their own guidelines. So Q. The next sentence in this second full paragraph gives a little more detail about the 	12 13 14 15 16 17 18 19 20	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.
12 13 14 15 16 17 18 19 20 21	 if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its guidelines, WPATH doing its guidelines. I mean, everybody is doing their own guidelines. So Q. The next sentence in this second full paragraph gives a little more detail about the functions of NICE. It says, quote, "It conducts or 	12 13 14 15 16 17 18 19 20 21	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.
12 13 14 15 16 17 18 19 20 21 22	 if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its guidelines, WPATH doing its guidelines. I mean, everybody is doing their own guidelines. So Q. The next sentence in this second full paragraph gives a little more detail about the functions of NICE. It says, quote, "It conducts or contracts for technology assessments of new 	12 13 14 15 16 17 18 19 20 21 22	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.
12 13 14 15 16 17 18 19 20 21	 if you're going to have guidelines, it's all these independent groups that have to create them. And so guidelines in the U.S. are not coming from a you know, there's not a single payer and a single way of developing guidelines. We have different organizations: NASPGHAN doing its guidelines, WPATH doing its guidelines. I mean, everybody is doing their own guidelines. So Q. The next sentence in this second full paragraph gives a little more detail about the functions of NICE. It says, quote, "It conducts or 	12 13 14 15 16 17 18 19 20 21	MR. BROOKS: That is just fine. MS. LEVI: It is close to 12:45. Shoot for half an hour? MR. BROOKS: That's fine.

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 40 of 58

CONFIDENTIAL

1	Page 150	1	Page 152 searches that were done for scientific evidence?
$\begin{vmatrix} 1\\ 2 \end{vmatrix}$	AFTERNOON SESSION 1:20 p.m.	-	
	MS. LEVI: I will take a rough. A couple	$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	MS. LEVI: Object as to form. A. I think I need to understand better what
	days is fine. BY MR. BROOKS:		
4		4	the like, what's not a systematic search, or
5	Q. Let me ask you, Dr. Lightdale, to find	5	whatever.
6	Exhibit 15, the "Clinical Practice Guidelines We Can	6	I'm not sure exactly how to answer that,
7	Trust." If you would turn in that document to Page		because I think there's a lot of things you think
8	2, which is a ways in, because it follows the	8	about when you're looking at clinical practice
9	preface.	9	guidelines. That's what I think this paragraph is
10	On Page 2 is the heading that says, "CPG,"	10	saying: There are a lot of things you have to think
11	Clinical Practice Guideline, "Development	11	about.
12	Challenges." And an inch and a half down, two	12	Q. I'm asking your opinion now, not what the
13	inches down in that is the sentence that begins,	13	paragraph is saying.
14	"Certain factors commonly undermine." Let me ask	14	If a group preparing a clinical practice
15	you to find that.	15	guideline performs systematic searches for relevant
16	A. Yes.	16	evidence, do you agree that appropriate transparency
17	Q. It reads, "Certain factors commonly	17	includes disclosing the nature of searches done?
18	undermine the quality and trustworthiness of	18	MS. LEVI: Object.
19	CPG's." And you understand that to refer to	19	A. So I think it's just again, for me,
20	clinical practice guidelines, correct?	20	these are, like, sort of abstract questions, and I
21	A. Yes.	21	would need to get more specifics, I think, in order
22	Q. And it goes on to list factors that	22	to understand what we're trying to get at here, is
23	undermine quality and trustworthiness, including	23	the bottom line.
24	"lack of transparency of development groups'	24	So for me, there's lots of things you're
	Page 151		Page 153
1	methodologies (particularly with respect to evidence	1	thinking about, and it's really important that
2	methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)."	2	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking
	methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to		thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have
2 3 4	methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest."	2 3 4	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm
2 3 4 5	methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed	2 3 4 5	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline.
2 3 4 5 6	methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to?	2 3 4 5 6	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that.
2 3 4 5 6 7	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. 	2 3 4 5	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good
2 3 4 5 6	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a 	2 3 4 5 6 7 8	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with
2 3 4 5 6 7 8 9	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and 	2 3 4 5 6 7 8 9	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes
2 3 4 5 6 7 8 9 10	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do 	2 3 4 5 6 7 8 9 10	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has
2 3 4 5 6 7 8 9 10 11	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the 	2 3 4 5 6 7 8 9 10 11	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence?
2 3 4 5 6 7 8 9 10 11 12	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice 	2 3 4 5 6 7 8 9 10 11 12	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object.
2 3 4 5 6 7 8 9 10 11 12 13	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of 	2 3 4 5 6 7 8 9 10 11 12 13	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is
2 3 4 5 6 7 8 9 10 11 12 13 14	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for 	2 3 4 5 6 7 8 9 10 11 12 13 14	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for instance, the PICO factors? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for instance, the PICO factors? MS. LEVI: Object as to form. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline, for instance, the PICO factors? MS. LEVI: Object as to form. A. I think this is a list of things you have 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the different databases?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline, for instance, the PICO factors? MS. LEVI: Object as to form. A. I think this is a list of things you have to be thinking about, and there's not any one 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the different databases? Q. No, that wasn't my question.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for instance, the PICO factors? MS. LEVI: Object as to form. A. I think this is a list of things you have to be thinking about, and there's not any one absolute. So I'm not sure I totally agree that 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the different databases? Q. No, that wasn't my question. MR. BROOKS: Let me ask the reporter to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for instance, the PICO factors? MS. LEVI: Object as to form. A. I think this is a list of things you have to be thinking about, and there's not any one absolute. So I'm not sure I totally agree that that's how one defines a good clinical guideline. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the different databases? Q. No, that wasn't my question. MR. BROOKS: Let me ask the reporter to read back my question.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for instance, the PICO factors? MS. LEVI: Object as to form. A. I think this is a list of things you have to be thinking about, and there's not any one absolute. So I'm not sure I totally agree that that's how one defines a good clinical guideline. Q. You would consider, would you not, that 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the different databases? Q. No, that wasn't my question. MR. BROOKS: Let me ask the reporter to read back my question. (* Question read)
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for instance, the PICO factors? MS. LEVI: Object as to form. A. I think this is a list of things you have to be thinking about, and there's not any one absolute. So I'm not sure I totally agree that that's how one defines a good clinical guideline. Q. You would consider, would you not, that appropriate transparency in connection with the 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the different databases? Q. No, that wasn't my question. MR. BROOKS: Let me ask the reporter to read back my question. (* Question read) A. I would say not in and of itself. That's
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 methodologies (particularly with respect to evidence quality and strength of recommendation appraisals)." And then a few lines farther below, it refers to "unmanaged conflicts of interest." Do you see the various things I've pointed to? A. "Unmanaged conflicts of interest." Yes. Q. Okay. On the lack of transparency as a factor that can undermine the quality and trustworthiness of a clinical practice guideline, do you agree that suitable transparency in the development of a reliable clinical practice guideline includes disclosure of the design of searches for evidence that were done, including, for instance, the PICO factors? MS. LEVI: Object as to form. A. I think this is a list of things you have to be thinking about, and there's not any one absolute. So I'm not sure I totally agree that that's how one defines a good clinical guideline. Q. You would consider, would you not, that appropriate transparency in connection with the development of a clinical practice guideline will, 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 thinking about, and it's really important that that's the way I'm approaching things. I'm thinking about lots of different things, and I have to have all of them in order to decide whether or not I'm dealing with a good clinical practice guideline. Q. Let's see if you want to stick with that. * Do you have an opinion as to whether good practice and transparency in connection with preparing a clinical practice guideline includes disclosure of the databases that the team has searched for relevant evidence? MS. LEVI: Object. A. So the question that you are asking is, is the definition of transparency of the systematic search that they list the actual, whatever, PubMed, Cochrane, whatever that they did, the MBase, the different databases? Q. No, that wasn't my question. MR. BROOKS: Let me ask the reporter to read back my question. (* Question read)

39 (Pages 150 - 153)

	Page 154		Page 156
1	transparency. I asked you whether good practice	1	review?
2	includes disclosing the databases that you searched	2	A. So when I have done systematic reviews or
3	for relevant evidence.	3	been a part of systematic reviews, generally we've
4	MS. LEVI: Object as to form.	4	worked with somebody who's performed the systematic
5	A. I'm getting lost in the question, but not	5	review for us, usually a librarian.
6	in and of itself is listing the places you searched.	6	And then what you've got is, Okay, we were
7	Q. Would you agree that good practice in	7	given this number of papers that might or might not
8	connection with preparing a clinical practice	8	meet our criteria, and then we've gone through and
9	guideline includes, if the team has used established	9	we've made decisions about which ones we're
10	criteria for rating the strength of evidence,	10	including or not including, and we wind up with, in
11	disclosing the ratings that were assigned?	11	the end, Okay, we included X number, and then you
12	MS. LEVI: Object as to form.	12	move from there, where we've reviewed it.
13	A. I think there are lots of ways to do	13	And so you've sort of gone through a
14	guidelines. So the important thing is that	14	process. So the systematic review starts the
15	you basically put out what your process is going to	15	process, and then you have to move through it. And
16	be, and then you follow it.	16	we've usually explained that in some place, you
17	Q. That's it? That's the sum total of your	17	know, either in a figure or in a paragraph, in text.
18	opinion as to what constitutes good practice in	18	Q. * If a team developing clinical practice
19	forming and creating a clinical practice guideline?	19	guidelines has commissioned systematic reviews that
20	MS. LEVI: Object as to form.	20	resulted in GRADE ratings of the quality of evidence
21	A. I think there are now lots of groups,	21	on certain topics relevant to the clinical practice
22	including this group and including other groups,	22	guideline, would you agree with me that it would
23	that are saying, "Okay, let's go through different	23	violate principles of transparency not to make those
24	ways of measuring guidelines in trying to decide."	24	ratings available publicly?
	D 155		
1	Page 155 Dut they're also aware of all the different	1	Page 157
1	But they're also aware of all the different	1	MS. LEVI: Object as to form.
2	But they're also aware of all the different things that go into guidelines. So there isn't one	2	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it
23	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good	2 3	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made,
2 3 4	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing	2 3 4	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when
2 3 4 5	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the	2 3 4 5	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it
2 3 4 5 6	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline.	2 3 4 5 6	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important.
2 3 4 5 6 7	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check?	2 3 4 5 6 7	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the
2 3 4 5 6 7 8	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form.	2 3 4 5 6	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give
2 3 4 5 6 7	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex.	2 3 4 5 6 7 8	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not
2 3 4 5 6 7 8 9	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form.	2 3 4 5 6 7 8 9	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give
2 3 4 5 6 7 8 9 10	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing	2 3 4 5 6 7 8 9 10	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that
2 3 4 5 6 7 8 9 10 11	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of	2 3 4 5 6 7 8 9 10 11	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about.
2 3 4 5 6 7 8 9 10 11 12	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you	2 3 4 5 6 7 8 9 10 11 12	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways
2 3 4 5 6 7 8 9 10 11 12 13	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency	2 3 4 5 6 7 8 9 10 11 12 13	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to
2 3 4 5 6 7 8 9 10 11 12 13 14	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic	2 3 4 5 6 7 8 9 10 11 12 13 14	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different
2 3 4 5 6 7 8 9 10 11 12 13 14 15	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic reviews be disclosed?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different ways to do it. So, again, without getting into the specifics, I can't really understand what I'm going
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic reviews be disclosed? MS. LEVI: Object as to form. A. I'm not sure what you mean by "results of the systematic reviews." Like, what is that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different ways to do it. So, again, without getting into the specifics, I can't really understand what I'm going to be commenting on here. So
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic reviews be disclosed? MS. LEVI: Object as to form. A. I'm not sure what you mean by "results of the systematic reviews." Like, what is that "results of the systematic reviews"?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different ways to do it. So, again, without getting into the specifics, I can't really understand what I'm going to be commenting on here. So MR. BROOKS: Let me ask the reporter to read
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic reviews be disclosed? MS. LEVI: Object as to form. A. I'm not sure what you mean by "results of the systematic reviews." Like, what is that "results of the systematic reviews"? Q. You have performed systematic you've	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different ways to do it. So, again, without getting into the specifics, I can't really understand what I'm going to be commenting on here. So MR. BROOKS: Let me ask the reporter to read back my question.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic reviews be disclosed? MS. LEVI: Object as to form. A. I'm not sure what you mean by "results of the systematic reviews." Like, what is that "results of the systematic reviews"? Q. You have performed systematic you've participated in performing systematic reviews?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different ways to do it. So, again, without getting into the specifics, I can't really understand what I'm going to be commenting on here. So MR. BROOKS: Let me ask the reporter to read back my question. (* Question read)
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic reviews be disclosed? MS. LEVI: Object as to form. A. I'm not sure what you mean by "results of the systematic reviews." Like, what is that "results of the systematic reviews"? Q. You have performed systematic you've participated in performing systematic reviews? A. I have.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different ways to do it. So, again, without getting into the specifics, I can't really understand what I'm going to be commenting on here. So MR. BROOKS: Let me ask the reporter to read back my question. (* Question read) A. It's a very long question. So there's
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	But they're also aware of all the different things that go into guidelines. So there isn't one thing that you have to do that makes a good guideline. It's you sort of look at the whole thing that happened and then decide on the strength of the guideline. Q. So it's just kind of a gut check? MS. LEVI: Object as to form. A. I think it's complex. Q. If a team, in connection with preparing guidelines, commissioned the performance of systematic reviews of certain topics, would you agree that good practice with regard to transparency requires that the results of those systematic reviews be disclosed? MS. LEVI: Object as to form. A. I'm not sure what you mean by "results of the systematic reviews." Like, what is that "results of the systematic reviews"? Q. You have performed systematic you've participated in performing systematic reviews?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. LEVI: Object as to form. A. I don't agree with that. I don't think it violates principles. It's a decision that was made, or, frankly, it may have been at a moment when people were you know, didn't realize that it would be important. I think there's been a lot going on in the field, and so there hasn't been this, You must give the GRADE ratings exactly the way it's really not where we are. It's just becoming something that people are talking more about. So, again, there are many different ways people have put out guidelines and so many ways to put out your recommendations and I think different ways to do it. So, again, without getting into the specifics, I can't really understand what I'm going to be commenting on here. So MR. BROOKS: Let me ask the reporter to read back my question. (* Question read)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 42 of 58

CONFIDENTIAL

	D 170		5
1	Page 158		Page 160
	ratings next to the recommendations.	$\begin{vmatrix} 1 \\ 2 \end{vmatrix}$	I mean, there's lots of contexts in which
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	Q. No. That's not my question.A. Okay. So maybe I can	$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	you might make a decision that a systematic review didn't get what you needed and you would go back and
	Q. Does it violate principles of transparency	4	do it again.
4	not to disclose those GRADE ratings in any way,	5	-
5	shape or form?	6	So if that's what we're asking or I'm not sure if that's what you're asking. I think
6	MS. LEVI: Object as to form.	7	there are reasons that a systematic review is simply
8	A. Not to my knowledge.	8	not included in the guideline.
9	Q. If an organization, for the purposes of	9	Q. That's not what I'm asking.
10	preparing clinical practice guidelines, commissions	10	A. Okay.
11	an independent team to conduct systematic reviews	11	Q. If an organization such as WPATH, preparing
11	for the purpose of informing those guidelines, is it	11	clinical practice guidelines, commissioned
12	consistent with principles of transparency for that	12	systematic reviews to be performed by a separate
13	sponsoring organization to prevent the publication	13	entity, those reviews are done and delivered to the
14	of the results of the systematic review?	14	sponsoring organization, is it, in your view,
15	MS. LEVI: Object as to form.	15	consistent with ethics and transparency for the
10	A. Not to my knowledge.	17	sponsoring organization to publicly deny that the
18	Q. * If an organization preparing clinical	18	systematic views were in fact done?
10	practice guidelines commissions systematic reviews	10	MS. LEVI: I'm going to object as to form.
20	on certain topics from an independent team and	20	And also the question has been asked a number of
20	receives those systematic reviews, is it consistent	20	times.
21	with ethics and transparency, in your view, for that	$\begin{vmatrix} 21\\22 \end{vmatrix}$	I just want to say, answer it if you can.
22	organization to publicly deny that the systematic	22	A. Yeah, I guess I'm having trouble
	reviews were done?	23	understanding what would be the context in which
		12.	anderstanding what would be the context in which
	D 170		D 144
1	Page 159 MS_LEVI: Object as to form	1	Page 161
1	MS. LEVI: Object as to form.	1	they would be asked, "Did you do a systematic
2	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I	1 2 3	they would be asked, "Did you do a systematic review?", and then they would publicly deny it.
23	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context	3	they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This
2 3 4	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly	3 4	they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any
2 3 4 5	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be.	3 4 5	they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just
2 3 4	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent	3 4 5 6	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question?
2 3 4 5	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review,	3 4 5 6 7	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question.
2 3 4 5 6 7 8	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained	3 4 5 6 7 8	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So
2 3 4 5 6 7 8 9	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now	3 4 5 6 7 8 9	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question
2 3 4 5 6 7 8 9 10	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny?	3 4 5 6 7 8 9 10	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can.
2 3 4 5 6 7 8 9 10 11	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to	3 4 5 6 7 8 9 10 11	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay.
2 3 4 5 6 7 8 9 10 11 12	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back.	3 4 5 6 7 8 9 10 11 12	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't
2 3 4 5 6 7 8 9 10 11 12 13	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read)	3 4 5 6 7 8 9 10 11	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such.
2 3 4 5 6 7 8 9 10 11 12	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back.	3 4 5 6 7 8 9 10 11 12 13	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't
2 3 4 5 6 7 8 9 10 11 12 13 14 15	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it?	3 4 5 6 7 8 9 10 11 12 13 14	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4.
2 3 4 5 6 7 8 9 10 11 12 13 14	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it? Q. Yes.	3 4 5 6 7 8 9 10 11 12 13 14 15	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4. There, in Paragraph 24 on Page 8, you
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it? Q. Yes. A. It wouldn't you don't have to use a	3 4 5 6 7 8 9 10 11 12 13 14 15 16	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4. There, in Paragraph 24 on Page 8, you discuss the Delphi process, and you describe it as a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it? Q. Yes. A. It wouldn't you don't have to use a systematic review when you publish your guideline.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4. There, in Paragraph 24 on Page 8, you discuss the Delphi process, and you describe it as a "well-established methodology." We've talked about
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it? Q. Yes. A. It wouldn't you don't have to use a systematic review when you publish your guideline. I actually think, no, that that in my opinion,	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4. There, in Paragraph 24 on Page 8, you discuss the Delphi process, and you describe it as a "well-established methodology." We've talked about it a bit. We've discussed the voting process.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it? Q. Yes. A. It wouldn't you don't have to use a systematic review when you publish your guideline.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4. There, in Paragraph 24 on Page 8, you discuss the Delphi process, and you describe it as a "well-established methodology." We've talked about
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it? Q. Yes. A. It wouldn't you don't have to use a systematic review when you publish your guideline. I actually think, no, that that in my opinion, you've done a systematic review, you might say,	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4. There, in Paragraph 24 on Page 8, you discuss the Delphi process, and you describe it as a "well-established methodology." We've talked about it a bit. We've discussed the voting process.
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ \end{array} $	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it? Q. Yes. A. It wouldn't you don't have to use a systematic review when you publish your guideline. I actually think, no, that that in my opinion, you've done a systematic review, you might say, "Gee, that wasn't good enough," or "That didn't get	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4. There, in Paragraph 24 on Page 8, you discuss the Delphi process, and you describe it as a "well-established methodology." We've talked about it a bit. We've discussed the voting process.
$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ \end{array}$	MS. LEVI: Object as to form. A. Again, you're describing scenarios that I almost can't imagine, so I am not sure the context in which I mean, I don't know. I'm not exactly sure what this would be. My understanding is you have an independent group that is now has done the systematic review, and the other group doesn't wait. You explained something, and you said the first group should now deny? MR. BROOKS: Let me ask the reporter to read the question back. (* Question read) A. Which organization? The one that commissioned it? Q. Yes. A. It wouldn't you don't have to use a systematic review when you publish your guideline. I actually think, no, that that in my opinion, you've done a systematic review, you might say, "Gee, that wasn't good enough," or "That didn't get what we wanted to," or "It didn't" "Actually, we forgot a search term. Let's go back and do it	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	they would be asked, "Did you do a systematic review?", and then they would publicly deny it. I just don't get what happened here. This would this is guidelines are not usually any need to deny anything. It's just Q. Are you unable to answer your question? A. I would be unable to answer your question. Not following it. So MS. LEVI: You can only answer a question if you can. THE WITNESS: Okay. MS. LEVI: It's fine. If not, if you can't answer it, then respond as such. Q. Let me ask you to find your expert report, which is Exhibit 4. There, in Paragraph 24 on Page 8, you discuss the Delphi process, and you describe it as a "well-established methodology." We've talked about it a bit. We've discussed the voting process. We've discussed anonymity. I don't want to rehash all that. In 23, you quote Dr. Laidlaw as saying

41 (Pages 158 - 161)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 43 of 58

CONFIDENTIAL

	Page 162		Page 164
1	A. Yes.	1	WPATH methodology web page that suggested to you
2	Q. Now, am I correct that Delphi is a process	2	that WPATH leadership made substantive changes to
3	which could be used to achieve consensus or to	3	the guidelines after the completion of the Delphi
4	attempt to achieve consensus on either evidence-	4	process that they describe?
5	based recommendations or recommendations based	5	MS. LEVI: Object as to form.
6	simply on expert opinion? It could be used for	6	A. All I read was the website that explained
7	either of those, correct?	7	their process. I don't recall anything saying about
8	A. That's my understanding.	8	making any changes after the fact.
9	Q. And in one case the output would be	9	Q. As a scientist and clinician, if you read a
10	evidence based, and in the other case the output	10	set of guidelines in which the methodology said that
11	would not be evidence based, right?	11	all the recommendations were approved through a
12	A. I mean, Delphi, again, is a process for	12	Delphi process, and in fact some of those
13	developing consensus.	13	recommendations had been materially altered through
14	Q. And using Delphi doesn't tell you anything	14	a non-anonymous process after the Delphi process,
15	one way or the other as to whether	15	that would cause you serious concern, would it not?
16	A. Correct.	16	MS. LEVI: Object as to form.
17	Q the output is evidence based?	17	A. Not necessarily. Having been through it,
18	Okay. I just wanted to clarify that.	18	what I would need is an understanding, some context
19	And you, yourself, have, on multiple	19	around what changes were made and why.
20	occasions, participated in Delphi processes?	20	Q. Why, given the importance of the Delphi
21	A. Yes.	21	process and the anonymity of the Delphi process, do
22	Q. Given the nature of a Delphi process and	22	you need more context to form an opinion as to
23	the importance of anonymity as you've described it,	23	whether post hoc changes through a non-anonymous
24	would it be appropriate for the leadership of a	24	process would violate principles and cause you
	Page 163		Page 165
1	clinical practice guideline project to make	1	concern as a scientist and a clinician?
2	clinical practice guideline project to make substantive changes to guideline recommendations	2	concern as a scientist and a clinician? MS. LEVI: Object as to form.
23	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi	23	concern as a scientist and a clinician?MS. LEVI: Object as to form.A. So Delphi allows for some work to happen as
2 3 4	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process?	2 3 4	concern as a scientist and a clinician?MS. LEVI: Object as to form.A. So Delphi allows for some work to happen as you're getting to the final bits. And in
2 3 4 5	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object.	23	concern as a scientist and a clinician?MS. LEVI: Object as to form.A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you
2 3 4 5 6	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes	2 3 4 5 6	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort
2 3 4 5 6 7	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi	2 3 4 5 6 7	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically
2 3 4 5 6 7 8	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed.	2 3 4 5 6 7 8	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process.
2 3 4 5 6 7 8 9	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive	2 3 4 5 6 7 8 9	concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within
2 3 4 5 6 7 8 9 10	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes."	2 3 4 5 6 7 8 9 10	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the
2 3 4 5 6 7 8 9 10 11	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form.	2 3 4 5 6 7 8 9 10 11	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done.
2 3 4 5 6 7 8 9 10 11 12	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's	2 3 4 5 6 7 8 9 10 11 12	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi
2 3 4 5 6 7 8 9 10 11 12 13	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said.	2 3 4 5 6 7 8 9 10 11 12 13	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement
2 3 4 5 6 7 8 9 10 11 12 13 14	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if	2 3 4 5 6 7 8 9 10 11 12 13 14	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi
2 3 4 5 6 7 8 9 10 11 12 13 14 15	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again? MS. LEVI: Object as to form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what you're trying to explain that you did. So	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again? MS. LEVI: Object as to form. A. I personally have not.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what you're trying to explain that you did. So Q. Is your understanding, based on what you 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again? MS. LEVI: Object as to form. A. I personally have not. Q. Okay.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what you're trying to explain that you did. So Q. Is your understanding, based on what you read from the WPATH web page, that all the WPATH 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again? MS. LEVI: Object as to form. A. I personally have not. Q. Okay. Let me ask you to find Paragraph 31 of your
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	 clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what you're trying to explain that you did. So Q. Is your understanding, based on what you read from the WPATH web page, that all the WPATH recommendations and suggestions were approved 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again? MS. LEVI: Object as to form. A. I personally have not. Q. Okay. Let me ask you to find Paragraph 31 of your report. And there you stated, "Dr. Laidlaw also
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	 clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what you're trying to explain that you did. So Q. Is your understanding, based on what you read from the WPATH web page, that all the WPATH recommendations and suggestions were approved through a Delphi process? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again? MS. LEVI: Object as to form. A. I personally have not. Q. Okay. Let me ask you to find Paragraph 31 of your report. And there you stated, "Dr. Laidlaw also erroneously suggests that merely being a provider
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	 clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what you're trying to explain that you did. So Q. Is your understanding, based on what you read from the WPATH web page, that all the WPATH recommendations and suggestions were approved through a Delphi process? A. I don't remember if it was all of them, but 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again? MS. LEVI: Object as to form. A. I personally have not. Q. Okay. Let me ask you to find Paragraph 31 of your report. And there you stated, "Dr. Laidlaw also erroneously suggests that merely being a provider who treats gender dysphoria creates a 'conflict of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 clinical practice guideline project to make substantive changes to guideline recommendations after they have been approved through the Delphi process? MS. LEVI: Object. A. So not I mean, there are little changes people can make after you've gone through a Delphi process. So, for instance, grammar can get changed. Q. In my question I said "substantive changes." MS. LEVI: Object as to form. A. That's what I think you said. So that's what I thought you said. So Delphi is a methodology, and ideally, if you're going to follow it, you will come to a consensus around a statement. And that's what you're trying to explain that you did. So Q. Is your understanding, based on what you read from the WPATH web page, that all the WPATH recommendations and suggestions were approved through a Delphi process? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 concern as a scientist and a clinician? MS. LEVI: Object as to form. A. So Delphi allows for some work to happen as you're getting to the final bits. And in particular I've been through the moment when you realize you've got two statements that can be sort of made into one, or things like that that basically will help simplify your process. So I think there are even allowances within Delphi to be able to keep working after the iterative process is done. Q. Have you been involved in any Delphi process where, at a late stage, a revised statement or recommendation was sent back through the Delphi process again? MS. LEVI: Object as to form. A. I personally have not. Q. Okay. Let me ask you to find Paragraph 31 of your report. And there you stated, "Dr. Laidlaw also erroneously suggests that merely being a provider who treats gender dysphoria creates a 'conflict of interest' with respect to participating in the

42 (Pages 162 - 165)

		-	
	Page 166		Page 168
1	medical ethics or science," close quote.	1	and disclosing and managing conflicts of interest,
2	Now, you would agree with me, would you	2	it's important to transparency that a clinical
3	not, Dr. Lightdale, that being a provider who treats	3	practice guideline development team does follow the
4	gender dysphoria is likely to give a physician some	4	protocols that they state that they followed?
5	financial interest in some potential financial	5	MS. LEVI: Object as to form.
6	interest in what procedures are or are not approved	6	A. So right. So I think that there are
7	by the guidelines?	7	there's a framework here, and there's lots of
8	MS. LEVI: Object as to form.	8	different ways that I can put that framework into
9	A. No. No. I don't agree with that	9	action. But I would say, if you're going to state
10	statement.	10	something, then you followed it.
11	Q. Why is that?	11	Q. If you state that you followed it, you
12	A. I think physicians who treat conditions	12	should follow it; that's what you're saying,
13	I mean, we're talking here about gender dysphoria,	13	correct?
14	but I treat conditions. I am treating a patient for	14	MS. LEVI: Object as to form.
15	what they have as a condition. That's what I'm	15	A. I mean, this is the methods of what they
16	supposed to do as a health care provider.	16	did. So they are describing their methods.
17	So I don't think my financial interest is	17	Q. And my question is, if they describe their
18	in providing treatment to patients. It's my	18	methods as incorporating recommendations with
19	profession.	19	respect to conflict-of-interest policy from the
20	Q. I could flip back to it, but let's see if	20	Institute of Medicine document, then it would
21	we can do it without.	21	violate principles of transparency if in fact they
22	You recall that we looked at the SOC-8	22	did not follow those conflict of interest
23	methodology appendix which had language that stated	23	principles?
24	that that team relied on recommendations developed	24	MS. LEVI: Object as to form.
	Page 167		Page 169
1	Page 167 by the National Academy of Medicine and cited the	1	Page 169 A. I think there are lots of ways to do
1 2	Page 167 by the National Academy of Medicine and cited the document we've looked at from the Institute of	1 2	A. I think there are lots of ways to do
	by the National Academy of Medicine and cited the document we've looked at from the Institute of		A. I think there are lots of ways to do conflicts of interest, and I've personally filled
2	by the National Academy of Medicine and cited the	2	A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are
23	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest.	2 3	A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways.
2 3 4	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go	2 3 4	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's
2 3 4 5	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest.	2 3 4 5 6	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe
2 3 4 5 6 7	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't	2 3 4 5 6	A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but
2 3 4 5 6	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5.	2 3 4 5 6 7	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is.
2 3 4 5 6 7 8	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches	2 3 4 5 6 7 8	A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but
2 3 4 5 6 7 8 9	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads,	2 3 4 5 6 7 8 9	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the
2 3 4 5 6 7 8 9 10	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8	2 3 4 5 6 7 8 9 10	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15.
2 3 4 5 6 7 8 9 10 11	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice	2 3 4 5 6 7 8 9 10 11 12	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me.
2 3 4 5 6 7 8 9 10 11 12	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of	2 3 4 5 6 7 8 9 10 11 12 5 13	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me.
2 3 4 5 6 7 8 9 10 11 12 13	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that	2 3 4 5 6 7 8 9 10 11 12	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the
2 3 4 5 6 7 8 9 10 11 12 13 14	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest	2 3 4 5 6 7 8 9 10 11 12 5 13 14	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency."
2 3 4 5 6 7 8 9 10 11 12 13 14 15	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process."	2 3 4 5 6 7 8 9 10 11 12 5 13 14 15 16	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency." A. Okay.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process."	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency." A. Okay. Q. And on the following page, 77, the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." And then it cites the IOM document that we've looked at, correct?	2 3 4 5 6 7 8 9 10 11 12 5 13 14 15 16 17 18	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency." A. Okay. Q. And on the following page, 77, the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." And then it cites the IOM document that we've looked at, correct? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 5 13 14 15 16 17 18 19	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency." A. Okay. Q. And on the following page, 77, the paragraph at the bottom of the page begins, quote, "Transparency also requires statements regarding the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." And then it cites the IOM document that we've looked at, correct? A. Yes. Q. As well as a WHO document that I'm not	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency." A. Okay. Q. And on the following page, 77, the paragraph at the bottom of the page begins, quote, "Transparency also requires statements regarding the development team members' clinical experience, and
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." And then it cites the IOM document that we've looked at, correct? A. Yes. Q. As well as a WHO document that I'm not going to take your time with.	2 3 4 5 6 7 8 9 10 11 12 5 13 14 15 16 17 18 19 20 21	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency." A. Okay. Q. And on the following page, 77, the paragraph at the bottom of the page begins, quote, "Transparency also requires statements regarding the development team members' clinical experience, and potential conflicts of interest, as well as the
$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ \end{array}$	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." And then it cites the IOM document that we've looked at, correct? A. Yes. Q. As well as a WHO document that I'm not going to take your time with. A. Okay.	2 3 4 5 6 7 8 9 10 11 12 5 13 14 15 16 17 18 19 20 21 22	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency." A. Okay. Q. And on the following page, 77, the paragraph at the bottom of the page begins, quote, "Transparency also requires statements regarding the development team members' clinical experience, and potential conflicts of interest, as well as the guideline's funding source(s)."
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	by the National Academy of Medicine and cited the document we've looked at from the Institute of Medicine in connection with both process and conflict of interest. Do you recall that, or do you want to go back to it? A. I don't Q. Let's find the exhibit, which is Exhibit 5. Can you turn to Page 247. Three inches down in the first column is the language that reads, "The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process." And then it cites the IOM document that we've looked at, correct? A. Yes. Q. As well as a WHO document that I'm not going to take your time with.	2 3 4 5 6 7 8 9 10 11 12 5 13 14 15 16 17 18 19 20 21	 A. I think there are lots of ways to do conflicts of interest, and I've personally filled out many conflict-of-interest forms, and there are lots of different ways. I don't think the IOM actually said there's one way to do it, as far as I know. Again, maybe it's in the book, but Q. Maybe it is. Why don't you find Exhibit 14, the Institute of Medicine MS. LEVI: I think that's 15. MR. BROOKS: How right you are. Pardon me. Exhibit 15. Thank you for the correction. Q. If you will turn to Page 76, you'll see the heading, "Establishing Transparency." A. Okay. Q. And on the following page, 77, the paragraph at the bottom of the page begins, quote, "Transparency also requires statements regarding the development team members' clinical experience, and potential conflicts of interest, as well as the

1	Page 170	1	Page 172
	Q. Do you agree with that statement?	1	publication.
2	A. Sure.	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	Do you see that language referring to
3	Q. And if you turn to Page 78, you'll see a	3	intellectual conflicts of interest?
4	heading, "Management of Conflict of Interest," and	4	A. Yes.
5	there, in the second full sentence, it states, "A	5	Q. And are you generally familiar with the
6	recent comprehensive review of conflict-of-interest	6	concept of intellectual as opposed to financial
7	policies of guideline development organizations	7	conflicts of interest?
8	yielded the following complementary descriptions of	8	A. Yes.
9	conflict of interest," close quote, and it goes on	9	Q. And you agree that intellectual conflicts
10	to quote two of what it's referred to as	10	of interest can be among the types of conflict of
11	"complementary descriptions."	11	interest that should be disclosed in connection with
12	I want to read to you the first. Quote, "A	12	a clinical practice guideline project?
13	divergence between an individual's private interests	13	MS. LEVI: Object as to form.
14	and his or her professional obligations such that an	14	A. I mean, I would say that is that's an
15	independent observer might reasonably question	15	opinion, and one I think I've come to. But, you
16	whether the individual's professional actions or	16	know, it's an evolving area. That's the other thing about that one.
17	decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue	17	
18		18	Q. If you look at Page 79, six line down, at the end of the line it begins a sentence as follows,
19 20	streams or community standing."	19 20	quote, "Direct financial commercial activities
20	Do you see that? A. Yeah.	$\frac{20}{21}$	include clinical services from which a committee
$\begin{vmatrix} 21\\22 \end{vmatrix}$		$21 \\ 22$	member derives a substantial portion of his or her
22	MS. LEVI: Take the time you need to review the document.	22	income; consulting; board membership for which
23	Q. My question for you is whether that		compensation of any type is received; serving as a
27	Q. Wy question for you is whether that	27	compensation of any type is received, serving as a
1	Page 171	1	Page 173
1	definition of a conflict of interest that IOM has	1	paid expert witness," and it goes on.
2	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of	2	paid expert witness," and it goes on. Do you see that language?
23	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest.	2 3	paid expert witness," and it goes on.Do you see that language?A. Yes.
2 3 4	definition of a conflict of interest that IOM hasquoted here is consistent with your understanding ofwhat constitutes a conflict of interest.A. Yes, this is consistent with what I think,	2 3 4	paid expert witness," and it goes on.Do you see that language?A. Yes.Q. And do you agree or disagree that a direct
2 3 4 5	definition of a conflict of interest that IOM hasquoted here is consistent with your understanding ofwhat constitutes a conflict of interest.A. Yes, this is consistent with what I think,which is really around this very important concept	2 3 4 5	paid expert witness," and it goes on.Do you see that language?A. Yes.Q. And do you agree or disagree that a direct financial commercial interest that can comprise a
2 3 4 5 6	definition of a conflict of interest that IOM hasquoted here is consistent with your understanding ofwhat constitutes a conflict of interest.A. Yes, this is consistent with what I think,which is really around this very important conceptof an independent observer might reasonably question	2 3 4 5 6	paid expert witness," and it goes on.Do you see that language?A. Yes.Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical
2 3 4 5 6 7	definition of a conflict of interest that IOM hasquoted here is consistent with your understanding ofwhat constitutes a conflict of interest.A. Yes, this is consistent with what I think,which is really around this very important conceptof an independent observer might reasonably questionwhether something is being motivated.	2 3 4 5 6 7	paid expert witness," and it goes on.Do you see that language?A. Yes.Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a
2 3 4 5 6 7 8	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these	2 3 4 5 6 7 8	paid expert witness," and it goes on.Do you see that language?A. Yes.Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income?
2 3 4 5 6 7 8 9	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of	2 3 4 5 6 7 8 9	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form.
2 3 4 5 6 7 8 9 10	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's	2 3 4 5 6 7 8 9 10	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is
2 3 4 5 6 7 8 9 10 11	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of	2 3 4 5 6 7 8 9 10 11	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I
2 3 4 5 6 7 8 9 10 11 12	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest.	2 3 4 5 6 7 8 9 10 11 12	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't
2 3 4 5 6 7 8 9 10 11 12 13	 definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the 	2 3 4 5 6 7 8 9 10 11 12 13	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or
2 3 4 5 6 7 8 9 10 11 12 13 14	 definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual 	2 3 4 5 6 7 8 9 10 11 12 13 14	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one. Number two is the way medicine works.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind." 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one. Number two is the way medicine works. You're getting paid for encounters. You're not
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind." And the following sentence says, quote,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one. Number two is the way medicine works. You're getting paid for encounters. You're not getting paid for, you know, doing anything specific.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind." And the following sentence says, quote, "Finally, intellectual conflicts of interest 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one. Number two is the way medicine works. You're getting paid for encounters. You're not getting paid for, you know, doing anything specific. You're just getting paid to see the patient.
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind." And the following sentence says, quote, "Finally, intellectual conflicts of interest specific to clinical practice guidelines are defined	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one. Number two is the way medicine works. You're getting paid for encounters. You're not getting paid for, you know, doing anything specific. You're just getting paid to see the patient. And then the third thing is, I don't think
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ \end{array} $	 definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind." And the following sentence says, quote, "Finally, intellectual conflicts of interest specific to clinical practice guidelines are defined as 'academic activities that create the potential 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one. Number two is the way medicine works. You're getting paid for encounters. You're not getting paid for, you know, doing anything specific. You're just getting paid to see the patient. And then the third thing is, I don't think that the National Academy of Sciences would have
$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ \end{array}$	 definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind." And the following sentence says, quote, "Finally, intellectual conflicts of interest specific to clinical practice guidelines are defined as 'academic activities that create the potential for an attachment to a specific point of view that 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one. Number two is the way medicine works. You're getting paid for encounters. You're not getting paid for, you know, doing anything specific. You're just getting paid to see the patient. And then the third thing is, I don't think that the National Academy of Sciences would have taken us down a route that means that experts in an
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ \end{array} $	 definition of a conflict of interest that IOM has quoted here is consistent with your understanding of what constitutes a conflict of interest. A. Yes, this is consistent with what I think, which is really around this very important concept of an independent observer might reasonably question whether something is being motivated. So for me and, again, it's got these complementary descriptions. I mean, there's lots of ways to think about it, but you have to think it's reasonable to think that there's conflict of interest. Q. The language goes on there to refer, in the next line, to, quote, "A financial or intellectual relationship that may impact an individual's ability to approach a scientific question with an open mind." And the following sentence says, quote, "Finally, intellectual conflicts of interest specific to clinical practice guidelines are defined as 'academic activities that create the potential 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 paid expert witness," and it goes on. Do you see that language? A. Yes. Q. And do you agree or disagree that a direct financial commercial interest that can comprise a conflict of interest includes providing clinical services from which a committee member derives a substantial portion of his or her income? MS. LEVI: Object as to form. A. So I disagree with, I think, how this is being characterized. And I will tell you that I think that many of us are salaried. So it doesn't matter if I bill if I do a particular thing or not, because I'm still going to get the same salary. That's number one. Number two is the way medicine works. You're getting paid for encounters. You're not getting paid for, you know, doing anything specific. You're just getting paid to see the patient. And then the third thing is, I don't think that the National Academy of Sciences would have

44 (Pages 170 - 173)

	D 174		D 174
1	Page 174	1	Page 176
	So I think we know we need experts in	1	talks about management through disclosure and is not
$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	guidelines and that those experts have to really be	$\begin{vmatrix} 2 \\ 2 \end{vmatrix}$	saying that everybody who has a conflict of interest
	doing the medicine in order to be able to be a part		is disqualified from participating in a guideline
4	of that process.	4	development process? You understand that, correct?
5	So I think what they're talking about there	5	A. Yes.
6	is, if you are, and I do, do some consulting, or you	6	Q. Okay. Now, my question for you is, is it
7	do have royalties or something like that, that's	7	consistent with your understanding that a physician,
8	where you must disclose, on a conflict-of-interest	8	who provides clinical services potentially affected
9	form, that you work with a company that actually has	9	by the guideline from which that individual derives
10	interest in a guideline going in a certain	10	a substantial proportion of his or her income, has a
11	direction.	11	financial conflict of interest of a type that needs
12	It's not about the practice of medicine.	12	management, perhaps through disclosure?
13	It's about what you're doing to the side of that	13	MS. LEVI: Object as to form.
14	that they're worrying about.	14	A. I don't think that's what they were trying
15	Q. Let me break out a couple of things that	15	to get at here. I think they're assuming that the
16	you said.	16	people on a guideline committee are experts in their
17	First, when it comes to fees for	17	field and do that type of medicine. So that was
18	procedures, is it your testimony that, when you	18	that's sort of an assumption. There's no point in
19	perform an endoscopic procedure, that there is not	19	being in a guideline-writing process if you don't
20	separate billing tagged to that procedure?	20	actually practice the medicine.
21	MS. LEVI: Object as to form.	21	So I think what they're getting at here is,
22	A. I mean, I submit a bill, but I myself will	22	are you going to be making money because you have
23	get the same salary whether I've submitted the bill,	23	stocks in something or you consult for something and
24	like or not. It's not I don't have like,	24	you'll get more money if you, you know, continue to
	Page 175		Page 177
1	Page 175 many of us, particularly in pediatrics and in	1	Page 177 consult, and people will be happy with you.
1 2		1 2	-
	many of us, particularly in pediatrics and in		consult, and people will be happy with you.
2	many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do	2	consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday.
23	many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to	23	consult, and people will be happy with you.Q. Dr. Coleman pardon me. That was Friday.What is your understanding of the language
2 3 4	many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So	2 3 4	consult, and people will be happy with you.Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the languageI directed you to that refers to providing, quote,
2 3 4 5	many of us, particularly in pediatrics and inacademic pediatrics, are not it has nothing to dowith how much or how little we bill. We're going toget our salaries. SoQ. Let's break that out.	2 3 4	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member
2 3 4 5	many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. SoQ. Let's break that out. It's the case, is it not, that in	2 3 4 5 6	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"?
2 3 4 5	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or 	2 3 4 5 6	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually
2 3 4 5 6 7 8	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite 	2 3 4 5 6 7 8	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial
2 3 4 5 6 7 8 9	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? 	2 3 4 5 6 7 8 9	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in
2 3 4 5 6 7 8 9 10	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. 	2 3 4 5 6 7 8 9 10	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're
2 3 4 5 6 7 8 9 10 11	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is 	2 3 4 5 6 7 8 9 10 11	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it
2 3 4 5 6 7 8 9 10 11 12	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being 	2 3 4 5 6 7 8 9 10 11 12	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it
2 3 4 5 6 7 8 9 10 11 12 13	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. 	2 3 4 5 6 7 8 9 10 11 12 13	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to
2 3 4 5 6 7 8 9 10 11 12 13 14	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure 	2 3 4 5 6 7 8 9 10 11 12 13 14	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure A. Specifically. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income."
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure A. Specifically. Q. By specific procedure? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income." And I guess where I'm thinking is that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure A. Specifically. Q. By specific procedure? A. Sure. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income." And I guess where I'm thinking is that what they're talking about there, I think, is
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure A. Specific procedure? A. Sure. Q. Second, it's by no means the case, is it, 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income." And I guess where I'm thinking is that what they're talking about there, I think, is someone who is going to make a lot of money if they
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure A. Specifically. Q. By specific procedure? A. Sure. Q. Second, it's by no means the case, is it, that all physicians are salaried, such that their 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income." And I guess where I'm thinking is that what they're talking about there, I think, is someone who is going to make a lot of money if they do something I mean, basically the guideline is
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure A. Specifically. Q. By specific procedure? A. Sure. Q. Second, it's by no means the case, is it, that all physicians are salaried, such that their income does not depend on how many procedures they 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income." And I guess where I'm thinking is that what they're talking about there, I think, is someone who is going to make a lot of money if they do something I mean, basically the guideline is going to have them do something more, and so then
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure A. Specific procedure? A. Sure. Q. Second, it's by no means the case, is it, that all physicians are salaried, such that their income does not depend on how many procedures they perform? 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income." And I guess where I'm thinking is that what they're talking about there, I think, is someone who is going to make a lot of money if they do something I mean, basically the guideline is going to have them do something more, and so then they're going to do more of it, and now they're
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 many of us, particularly in pediatrics and in academic pediatrics, are not it has nothing to do with how much or how little we bill. We're going to get our salaries. So Q. Let's break that out. It's the case, is it not, that in connection with medical procedures, including or perhaps particularly surgeries, bills are quite specifically broken out by procedure? MS. LEVI: Object as to form. A. Our current health care system is absolutely about patient-facing activities being billed. Q. Specific procedure A. Sure. Q. Second, it's by no means the case, is it, that all physicians are salaried, such that their income does not depend on how many procedures they perform? A. This is true. Q. And you also understand, do you not, that 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	consult, and people will be happy with you. Q. Dr. Coleman pardon me. That was Friday. What is your understanding of the language I directed you to that refers to providing, quote, "clinical services from which a committee member derives a substantial portion of his or her income"? A. I mean, I think the sentence actually starts with "Direct financial commercial activities." And I would say, like everything in all of these papers, "may include," and then they're giving a whole list here of different things that it may include. And the first one that you're pointing to is "clinical services from which [you get] a substantial proportion of [your] income." And I guess where I'm thinking is that what they're talking about there, I think, is someone who is going to make a lot of money if they do something I mean, basically the guideline is going to have them do something more, and so then they're going to do more of it, and now they're going to make a lot of money.

45 (Pages 174 - 177)

	Page 178		Page 180
1	that's like, doesn't make any sense. It's about	1	conflict of interest consistent with your
2	commercialism, and we're talking I practice	2	understanding?
3	medicine.	3	A. I think so.
4	So I think what I can understand and what I	4	Q. And would you agree with me that, under
5	tend what I think of when I fill out a conflict-	5	that definition of an intellectual conflict of
6	of-interest form is, if I sit on a board, if I	6	interest, when it comes to pediatric endoscopy, you
7	consult, if I've been a paid witness, if I'm doing	7	have an intellectual conflict of interest?
8	industry-sponsored research, I have a financial	8	MS. LEVI: Object as to form.
9	interest in that company, and so then I need to	9	A. There are areas of my field where I may
10	disclose that on the disclosure form.	10	have intellectual conflict of interest, like within
11	Q. So as you sit here today, you really can't	11	it, that I have sure.
12	understand what the IOM was referring to when they	12	Q. Okay.
13	talk about clinical services?	13	A strong feelings on things, and I can
14	A. I think they're talking about clinical	14	Q. And strong published positions?
15	services that are affected when you sit on a board	15	A. Sure.
16	or you consult or you I think that's what this is	16	Q. Okay.
17	all getting at.	17	* For physicians who are compensated based
18	It's not getting at do you practice	18	on the revenue they generate for their practice, is
19	medicine. Like, do I practice pediatric GI? Yes,	19	it still your position that those physicians have no
20	of course. I sit on guidelines because I'm an	20	conflict of interest, financial conflict of
21	expert in that particular area.	21	interest, with respect to clinical practice
22	So, you know and I'm trying to remember	22	guidelines that may affect their practice?
23	where we started this, but financial conflict of	23	MS. LEVI: Object as to form.
24	interest is not practicing medicine. It's not	24	A. I may need the beginning of the question
	Page 179		Page 181
			-
1	treating patients. I mean, otherwise, we're	1	asked again. Sorry.
2	going	2	asked again. Sorry. (* Question read)
23	going MS. LEVI: You answered the question.	23	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a
2 3 4	goingMS. LEVI: You answered the question.Q. Let me ask you to look a little further	2 3 4	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in
2 3 4 5	goingMS. LEVI: You answered the question.Q. Let me ask you to look a little furtherdown, at a sentence that begins, "A person whose	2 3 4 5	asked again. Sorry.(* Question read)A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline
2 3 4 5 6	goingMS. LEVI: You answered the question.Q. Let me ask you to look a little furtherdown, at a sentence that begins, "A person whosework or professional group fundamentally."	2 3 4 5 6	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something
2 3 4 5 6 7	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? 	2 3 4 5 6 7	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is
2 3 4 5 6 7 8	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. 	2 3 4 5 6 7 8	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking?
2 3 4 5 6 7 8 9	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the 	2 3 4 5 6 7 8 9	 asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM
2 3 4 5 6 7 8 9 10	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. 	2 3 4 5 6 7 8 9 10	 asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't
2 3 4 5 6 7 8 9 10 11	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional 	2 3 4 5 6 7 8 9 10 11	 asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management.
2 3 4 5 6 7 8 9 10 11 12	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" 	2 3 4 5 6 7 8 9 10 11 12	 asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity
2 3 4 5 6 7 8 9 10 11 12 13	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for 	2 3 4 5 6 7 8 9 10 11 12 13	 asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or
2 3 4 5 6 7 8 9 10 11 12 13 14	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or 	2 3 4 5 6 7 8 9 10 11 12 13 14	 asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. Q. Go for it. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. Q. Go for it. A. It's actually easier for me, guys. 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of interest with respect to clinical practice
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. Q. Go for it. A. It's actually easier for me, guys. " fundamentally is jeopardized, or 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of interest with respect to clinical practice guidelines that may significantly affect that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. Q. Go for it. A. It's actually easier for me, guys. " fundamentally is jeopardized, or enhanced, by a guideline recommendation is said to 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of interest with respect to clinical practice guidelines that may significantly affect that physician's practice?
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. Q. Go for it. A. It's actually easier for me, guys. " fundamentally is jeopardized, or enhanced, by a guideline recommendation is said to have intellectual COI. Intellectual COI includes 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of interest with respect to clinical practice guidelines that may significantly affect that physician's practice? MS. LEVI: Object as to form.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. Q. Go for it. A. It's actually easier for me, guys. " fundamentally is jeopardized, or enhanced, by a guideline recommendation is said to have intellectual COI. Intellectual COI includes authoring a publication or acting as an investigator 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of interest with respect to clinical practice guidelines that may significantly affect that physician's practice? MS. LEVI: Object as to form. A. So what I'm having trouble with is, they
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. Q. Go for it. A. It's actually easier for me, guys. " fundamentally is jeopardized, or enhanced, by a guideline recommendation is said to have intellectual COI. Intellectual COI includes authoring a publication or acting as an investigator on a peer-reviewed grant directly related to 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of interest with respect to clinical practice guidelines that may significantly affect that physician's practice? MS. LEVI: Object as to form. A. So what I'm having trouble with is, they would have a conflict of interest in terms of
$\begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ \end{array}$	 going MS. LEVI: You answered the question. Q. Let me ask you to look a little further down, at a sentence that begins, "A person whose work or professional group fundamentally." Do you see that? A. Yes. Q. Let me ask you to read that and the following sentence. A. "A person whose work or professional group" MS. LEVI: Did you want her to read it for record or MR. BROOKS: Oh, might as well. Q. Go for it. A. It's actually easier for me, guys. " fundamentally is jeopardized, or enhanced, by a guideline recommendation is said to have intellectual COI. Intellectual COI includes authoring a publication or acting as an investigator 	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	asked again. Sorry. (* Question read) A. So what we're asking is, would it be a financial conflict of interest for a person in so-called private practice to sit on a guideline committee that may potentially recommend something that they then would be using in their practice? Is that what we're asking? Q. Again, we've talked about how IOM discussion of conflict of interest doesn't necessarily require exclusion as far as management. So my question isn't about any activity we're going to take. It's simply, do you agree or disagree that a physician whose income depends in significant part on revenues brought in from procedures performed has a financial conflict of interest with respect to clinical practice guidelines that may significantly affect that physician's practice? MS. LEVI: Object as to form. A. So what I'm having trouble with is, they

46 (Pages 178 - 181)

	Page 182		Page 184
1	where they are doing a lot of the procedure that's	1	that they had a process where they asked for both
2	going to be recommended in the guideline, or not	2	financial and nonfinancial conflicts of interest.
3	recommended in the guideline, that their practice	3	I mean, again, most of us are just starting
4	will be affected financially by that.	4	to do this.
5	I do believe in conflict-of-interest forms.	5	Q. What led you to believe that WPATH had a
6	You can be asked, "Do you own a practice?" I mean,	6	process that included asking for intellectual
7	that's you know, that's a reasonable thing to	7	conflicts of interest?
8	ask, "Do you own a company?" I think you get asked	8	A. It may have been talked about at some
9	that, "Do you own a company?", which private	9	point somebody brought it up.
10	practice technically would be.	10	Q. What do you mean by "somebody brought it
11	Again, for me, the difference is that I	11	up"?
12	don't think this is about being an expert in the	12	A. Isn't that here (indicating)? I don't
13	field. Like, that's just not one thing I'm not	13	remember.
14	asked, when I do these guidelines, "Are you a	14	Q. Do you recall seeing any document in which
15	gastroenterologist who's going to get affected by	15	WPATH claims to have identified
16	the guidelines?"	16	A. Maybe it's in this thing right here, to be
17	The answer is, of course, "Yes." Like,	17	honest, that we read it today.
18	everybody involved in the process is a	18	(Reviewing document) I think (reviewing
19	gastroenterologist who's going to get affected by	19	document)
20	the guidelines.	20	I'm actually getting all dizzy right now.
21	So it's not a financial conflict of	21	MS. LEVI: Do you want to take a break?
22	interest, what I do. Does that make any sense?	22	THE WITNESS: Well, yes.
23	Q. Dr. Lightdale, do you consider yourself to	23	A. But maybe I want to try to understand what
24	be an expert in conflict-of-interest principles?	24	we were talking about. Maybe it was way back at the
	Page 183		Page 185
1	Page 183 A. No.	1	-
1 2	A. No.	1 2	Page 185 beginning of the morning when we talked about this piece (indicating).
	A. No.Q. You, in fact and I think this follows	1 2 3	beginning of the morning when we talked about this piece (indicating).
2	A. No.Q. You, in fact and I think this followsfrom your earlier testimony, but let me ask.		beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about
2 3	A. No.Q. You, in fact and I think this followsfrom your earlier testimony, but let me ask.Am I correct that you have no knowledge as	3 4	beginning of the morning when we talked about this piece (indicating).
2 3 4	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or 	3 4 5	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So
2 3 4 5	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- 	3 4	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway
2 3 4 5 6	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, 	3 4 5 6	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So
2 3 4 5 6 7 8	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? 	3 4 5 6 7 8	 beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a
2 3 4 5 6 7	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is 	3 4 5 6 7	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes.
2 3 4 5 6 7 8 9 10	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading 	3 4 5 6 7 8 9 10	 beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room)
2 3 4 5 6 7 8 9 10 11	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the 	3 4 5 6 7 8 9 10 11	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for
2 3 4 5 6 7 8 9 10 11 12	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. 	3 4 5 6 7 8 9 10 11 12	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well?
2 3 4 5 6 7 8 9 10 11 12 13	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any 	3 4 5 6 7 8 9 10 11 12 13	 beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough.
2 3 4 5 6 7 8 9 10 11 12 13 14	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? 	3 4 5 6 7 8 9 10 11 12 13 14	 beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess)
2 3 4 5 6 7 8 9 10 11 12 13 14 15	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. 	3 4 5 6 7 8 9 10 11 12 13 14 15	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. Q. And you haven't looked at the SOC-8 itself 	3 4 5 6 7 8 9 10 11 12 13 14 15 16	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. Q. And you haven't looked at the SOC-8 itself to see what conflicts they in fact disclosed? 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context. THE WITNESS: Yes. So I want to make it
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. Q. And you haven't looked at the SOC-8 itself to see what conflicts they in fact disclosed? A. No. 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context. THE WITNESS: Yes. So I want to make it clear that, in preparing for today, I had seen a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. Q. And you haven't looked at the SOC-8 itself to see what conflicts they in fact disclosed? A. No. Q. You don't know whether you don't know 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context. THE WITNESS: Yes. So I want to make it clear that, in preparing for today, I had seen a document that was likely a conflict-of-interest
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. Q. And you haven't looked at the SOC-8 itself to see what conflicts they in fact disclosed? A. No. Q. You don't know whether you don't know 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context. THE WITNESS: Yes. So I want to make it clear that, in preparing for today, I had seen a document that was likely a conflict-of-interest document, and I think, again, such stuff I'm
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. Q. And you haven't looked at the SOC-8 itself to see what conflicts they in fact disclosed? A. No. Q. You don't know whether you don't know what proportion of the participants in the SOC-8 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context. THE WITNESS: Yes. So I want to make it clear that, in preparing for today, I had seen a document that was likely a conflict-of-interest document, and I think, again, such stuff I'm interested in intellectually, intellectual conflict
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. Q. And you haven't looked at the SOC-8 itself to see what conflicts they in fact disclosed? A. No. Q. You don't know whether you don't know what proportion of the participants in the SOC-8 development project had intellectual conflicts of interest of the type that we've discussed? 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context. THE WITNESS: Yes. So I want to make it clear that, in preparing for today, I had seen a document that was likely a conflict-of-interest document, and I think, again, such stuff I'm interested in intellectually, intellectual conflict of interest around this discussion.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. No. Q. You, in fact and I think this follows from your earlier testimony, but let me ask. Am I correct that you have no knowledge as to whether WPATH, in the course of creating SOC-8 or SOC-7, followed the Institute of Medicine conflict- of-interest principles spelled out in this document, Exhibit 15? A. The knowledge I have of what they did is from reading the websites and now, today, reading their methods, which sounded in line with what the National Academy of Sciences recommends. Q. But you haven't, for instance, seen any disclosure forms that were circulated within WPATH? A. No. Q. And you haven't looked at the SOC-8 itself to see what conflicts they in fact disclosed? A. No. Q. You don't know whether you don't know what proportion of the participants in the SOC-8 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	beginning of the morning when we talked about this piece (indicating). I can't remember. We were talking about I know, because I'm really interested in this intellectual conflict of interest discussion. So Anyway MR. BROOKS: Would you like to take a break? THE WITNESS: Yes. (The witness and Ms. Levi leave the room) THE COURT REPORTER: Ms. Levi has asked for a rough. Would you like one as well? MR. BROOKS: I would like a rough. (Recess) MS. LEVI: Dr. Lightdale wants to explain an earlier answer, give a context. THE WITNESS: Yes. So I want to make it clear that, in preparing for today, I had seen a document that was likely a conflict-of-interest document, and I think, again, such stuff I'm interested in intellectually, intellectual conflict

47 (Pages 182 - 185)

	Page 186		Page 188
1	as to whether the chair of SOC-8 had either	1	Q. And this was in connection with sedation
2	intellectual or financial conflicts of interest	2	generally?
3	relevant relating to treatment of gender	3	A. Yeah. This was not GI per se.
4	dysphoria?	4	Q. Okay. Let me ask you to turn to the second
5	A. I have no idea.	5	page of the document. In the first column, four
6	Q. And likewise, am I correct that you have no	6	inches down, there's a paragraph that begins,
7	idea as to whether the co-chairs of that project	7	"SCEPTER's previous study."
8	have financial or intellectual conflicts of	8	Do you see that?
9	interest?	9	A. Uh-huh.
10	A. I don't know that, no.	10	Q. And what is SCEPTER? It sounds like
11	Q. And the same is true with respect to the	11	something from a Bond movie.
12	chapter leads of each chapter team?	12	A. SCEPTER is Sedation Consortium on Endpoints
13	A. No idea.	13	and Procedures for Treatment, Education and
14	Q. Just because of law, I'm ticking these	14	Research. SCEPTER.
15	things off.	15	Q. Thank you.
16	And you have not formed any opinion as to	16	Late in the paragraph is a sentence and
17	the adequacy of the actual disclosures made by WPATH	17	feel free to read the whole paragraph. I'm going to
18	of conflicts of interest that may exist with respect	18	call your attention to sentence that begins, "While
19	to any participants in the process, have you?	19	safety is arguably the most important of the 6 IOM
20	A. I have no opinions.	20	domains, its measurement in clinical trials presents
21	Q. You get out of a whole lot of deposition by	21	complex problems and dilemmas."
22	just saying, "I have no opinions."	22	Do you see that language?
23	MR. BROOKS: Let me ask the reporter to	23	A. Yes.
24	mark as Exhibit 16 an article from 2018 entitled	24	Q. I'm going to ask you about that, and you
	Page 187		Page 189
1	"Evaluating Patient-Centered Outcomes in Clinical	1	can look at anything surrounding you want.
2	Trials of Procedural Sedation, Part 2," authors	2	The beginning of the paragraph refers to, I
3	lead author Denham Ward, and many authors, one of	3	think, a different document from the Institute of
4	whom is Dr. Lightdale.	4	Medicine, just to avoid any confusion.
5	(Document marked as Lightdale	5	Do you have an opinion as to well, are
6	Exhibit 16 for identification)	6	you able to explain to me why it's the case, if it
7	Q. Dr. Lightdale, I'm going to ask you first		is, that safety is arguably the most important
8	if you can identify this paper.		consideration being addressed here?
9	A. Yes.	9	A. So the group took the tack of saying that
10	Q. And can you explain to me your role in its	10	we were going to focus on safety, because, I think,
11	creation.	11	when you give sedation and anesthesia, you want to
12	A. So I was invited to be in this committee	12	avoid physical or psychological harm, and we thought
13	which was brought together by the FDA, but then	13	that was perhaps the most urgent thing you have to
14	represented a whole lot of stakeholders to come	14	think about with sedation, especially for
15	up with recommendations for what our endpoint	15	procedures.
16	what endpoints should be around treatment.	16	Q. Does sedation risk both physical and
17	This particular paper was around treatment,	17 18	psychological harm? A. Yes.
18	education and research. So endpoints for trials.	18	A. Tes.Q. Is one of those considered to be a more
10		19	O. IS ONE OF THOSE CONSIDERED TO BE A MORE
19	Q. And for the record, for the layman, can you		
20	explain to me what you mean by "endpoints."	20	serious problem than the other?
20 21	explain to me what you mean by "endpoints." A. Outcomes, what you could look at in a	20 21	serious problem than the other? MS. LEVI: Object as to form.
20 21 22	explain to me what you mean by "endpoints."A. Outcomes, what you could look at in a trial.	20 21 22	serious problem than the other?MS. LEVI: Object as to form.A. I think we considered them both. I mean,
20 21	explain to me what you mean by "endpoints." A. Outcomes, what you could look at in a	20 21	serious problem than the other? MS. LEVI: Object as to form.

48 (Pages 186 - 189)

1	Page 190 group simply chose to focus on safety, or is safety,	1	Page 192 Q. And maybe it could be we can focus on
$\begin{vmatrix} 1\\2 \end{vmatrix}$	for some recognized reason, the most important	$\begin{vmatrix} 1\\2 \end{vmatrix}$	this article or not. Let me ask more general
3	concern as physicians evaluate procedures?	3	question.
4	MS. LEVI: Object as to form.	4	In your experience, is it commonly the case
5	A. So SCEPTER was trying to decide what are	5	that systematic review searches are limited to
	good things to measure, and safety what this	6	articles published in English in the field of
6	sentence is really saying is safety is actually,	7	medicine?
8	whether or not I would actually say we agreed	8	MS. LEVI: Object as to form.
9	that other people could probably put together an	9	A. So my own personal experience has been that
	argument that one or the other IOM six domains was		we always think about should we include other
10	as important as safety.	10	-
11	But we said, "Okay, well, let's just assume	11	languages, and then we make a tactical decision not to.
		12	
13	it's really important. Actually measuring it is very hard." And so then that's what we said	13	Q. And is there a reason why it is generally accepted in the field as adequate to search only
14	we're really dealing with in this paper.		English language materials?
15 16	Q. Okay. In the second column on this same	15 16	MS. LEVI: Object as to form.
17	page, the second paragraph that begins in that	17	A. I think there's actually always a little
18	column starts, "For the systematic review of safety	18	bit of a discomfort with the fact that we're
19	studies."	19	limiting it just to English and that for example,
20	A. Uh-huh.	$\begin{vmatrix} 1 \\ 20 \end{vmatrix}$	there are billions of people that live in China and
20	Q. And am I correct that this group	20	India, and we're not including any medical
21	essentially commissioned an independent systematic	21 22	literature that comes out of those places, which
22	review of safety studies?	22	doesn't feel particularly comfortable. But there's
24	A. Yes.		just an economy of effort that you have to work
1	Page 191 Q. And it describes a few lines down it	1	Page 193 with, and
2	says, quote, "Only prospective randomized double-	$\begin{vmatrix} 1\\2 \end{vmatrix}$	Q. Is it also the case that, in many cases,
3	blind studies reported as full-text articles	3	science from countries that where the native
4	published in English were included." And I'm not	4	tongue is other than English are nevertheless
5	going to ask you again about blinding and	5	published in English?
6	randomizing.	6	A. Not necessarily.
7	Why did you consider it appropriate to	7	Q. I didn't say "necessarily." I said, is it
	restrict the search only to articles published in	8	often the case?
9	English?	9	MS. LEVI: Object as to form.
10	A. First off, I personally did not make	10	A. I don't actually know. I don't know.
11	decisions about this on my own. I was very much in	11	Q. All right.
12	the center of I'm really a middle person here of	12	You mentioned India. Do you have reason to
13	a very large group that was making decisions about	13	believe that important medical science coming out of
14	what we were going to do as a group.	14	India is published in any language other than
15	But there was a feeling, at least across	15	English?
16	all of sedation, procedural sedation and anesthesia,	16	A. I have no idea.
17	that you could get what we needed to get to you	17	Q. Okay. There's a lot of people there,
18	could get from randomized controlled trials.	18	but
19	And so, again, we made that decision	19	Let's go back, if we could, to the AGREE
20	that that's how we are going to do this particular	20	document, Exhibit 2, and I want to take you to Page
21	systematic review.	21	24.
21 22		21 22	24. There, at the top, the heading is, under
	systematic review.		
22	systematic review. Q. Sorry. My question was focused only on the	22	There, at the top, the heading is, under

49 (Pages 190 - 193)

	D 104		D 107
1	Page 194 considered in formulating the recommendations,"	1	Page 196 assuming that people are thinking about health
$\begin{vmatrix} 1\\2 \end{vmatrix}$	close quote.	$\begin{vmatrix} 1\\2 \end{vmatrix}$	benefits, side effects.
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	Do you see that?	3	I think well, I'll stop there.
4	A. Yes.	4	Q. You testified earlier that there are a
5		5	number of guidelines out there in the world that are
	Q. And do you agree that, before you relied on a clinical practice guideline, you would want to	6	not well done and perhaps not reliable, correct?
6	have good confidence that those who developed it had	7	A. Yes.
8	considered not just benefits but also side effects	8	Q. And so my question for you is, before you
9	and risks in formulating their recommendations?	9	rely on a guideline, do you want to see, in its
10	MS. LEVI: Object as to form.	10	text, evidence that those who prepared it have
11	-	11	considered side effects and risks?
	A. I mean, I think it's pretty yeah, it's	11	MS. LEVI: Object as to form.
12	pretty normal to think about all of that and to assume it's been thought about.	12	A. I don't think, when I go just in an
13	Q. Again, that's not what I asked.		
14		14	informal way to look at a guideline for guidance on
15	A. Okay.	15	what to do, that I am looking specifically to see
16	Q. I said, before you rely on a clinical	16	whether they what evidence that they've looked at risks and benefits. That's not I'm not able to
17	practice guideline, would you want to have good	17	
18	comfort that the team that developed it had	18	be that granular at that moment that I need the guideline.
19	considered not just benefits of a procedure or treatment but also the side effects and risks?	19 20	0
20 21			Q. Fair enough. And so now let me take us to
$\begin{vmatrix} 21\\22 \end{vmatrix}$	MS. LEVI: Object as to form.	21 22	the next step. Would you agree that, at least according to
	A. So when I personally evaluate like, look	22	
23 24	at a guideline, I want to feel comfortable that they have done that.	23	the AGREE II principles, that rigorous guidelines should, on their face, show evidence that the
24	nave done that.	24	should, on their face, show evidence that the
	Page 195	1	Page 197
1	Q. Thank you.	1	authors considered side effects and risks, as well
2	Q. Thank you. Under the "User's Manual Description," it	1 2 2	authors considered side effects and risks, as well as benefits, in connection with any particular
23	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health	1 2 3	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation?
2 3 4	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it	4	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form.
2 3 4 5	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the	4 5	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has
2 3 4 5 6	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion	4 5 6	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which
2 3 4 5 6 7	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes."	4 5 6 7	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that
2 3 4 5 6 7 8	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads,	4 5 6 7 8	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there.
2 3 4 5 6 7 8 9	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues	4 5 6 7 8 9	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly
2 3 4 5 6 7 8 9 10	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed."	4 5 6 7 8 9 10	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the
2 3 4 5 6 7 8 9 10 11	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline	4 5 6 7 8 9 10 11	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most
2 3 4 5 6 7 8 9 10 11 12	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you	4 5 6 7 8 9 10 11 12	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you
2 3 4 5 6 7 8 9 10 11 12 13	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence	4 5 6 7 8 9 10 11 12 13	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and
2 3 4 5 6 7 8 9 10 11 12 13 14	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been	4 5 6 7 8 9 10 11 12 13 14	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed?	4 5 6 7 8 9 10 11 12 13 14 15	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed? MS. LEVI: Object as to form.	4 5 6 7 8 9 10 11 12 13 14 15 16	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look, you'll be able to pick where a particular guideline
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed? MS. LEVI: Object as to form. A. So are we talking about what I want to see, 	4 5 6 7 8 9 10 11 12 13 14 15 16 17	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look, you'll be able to pick where a particular guideline is in that.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed? MS. LEVI: Object as to form. A. So are we talking about what I want to see, or we talking what this scale's about? 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look, you'll be able to pick where a particular guideline is in that. Q. At the bottom of the page is a section that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed? MS. LEVI: Object as to form. A. So are we talking about what I want to see, or we talking what this scale's about? Q. We're talking about what you want to see. 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look, you'll be able to pick where a particular guideline is in that. Q. At the bottom of the page is a section that says, "How to Rate." Do you see that?
$ \begin{array}{c} 2\\ 3\\ 4\\ 5\\ 6\\ 7\\ 8\\ 9\\ 10\\ 11\\ 12\\ 13\\ 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ \end{array} $	 Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed? MS. LEVI: Object as to form. A. So are we talking about what I want to see, or we talking what this scale's about? Q. We're talking about what you want to see. A. So I don't know that I if I'm smart 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look, you'll be able to pick where a particular guideline is in that. Q. At the bottom of the page is a section that says, "How to Rate." Do you see that? A. Uh-huh.
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	 Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed? MS. LEVI: Object as to form. A. So are we talking about what I want to see, or we talking what this scale's about? Q. We're talking about what you want to see. A. So I don't know that I if I'm smart enough that I'm looking carefully enough at 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look, you'll be able to pick where a particular guideline is in that. Q. At the bottom of the page is a section that says, "How to Rate." Do you see that? A. Uh-huh. Q. So, again, this is structure that I know
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\end{array} $	 Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed? MS. LEVI: Object as to form. A. So are we talking about what I want to see, or we talking what this scale's about? Q. We're talking about what you want to see. A. So I don't know that I if I'm smart enough that I'm looking carefully enough at guidelines to be able to say, "Oh, I evaluated that 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look, you'll be able to pick where a particular guideline is in that. Q. At the bottom of the page is a section that says, "How to Rate." Do you see that? A. Uh-huh. Q. So, again, this is structure that I know you testified earlier that your team used it as
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	 Q. Thank you. Under the "User's Manual Description," it states, quote, "The guideline should consider health benefits, side effects, and risks." And then it goes on to say, "For example, a guideline on the management of breast cancer may include a discussion on the overall effects on various final outcomes." And towards the end of that paragraph it reads, quote, "There should be evidence that these issues have been addressed." So my question for you is, in a guideline that you have confidence in, am I correct that you want to see, on the face of the guidelines, evidence that important side effects and risks have been considered and weighed? MS. LEVI: Object as to form. A. So are we talking about what I want to see, or we talking what this scale's about? Q. We're talking about what you want to see. A. So I don't know that I if I'm smart enough that I'm looking carefully enough at 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 authors considered side effects and risks, as well as benefits, in connection with any particular recommendation? MS. LEVI: Object as to form. A. Not exactly. I would say what AGREE II has done has said there's going to be degrees to which that evidence has you feel comfortable that that evidence is there. And so you're either going to strongly agree or strongly disagree or somewhere in the middle. And most people are going to most guidelines are going to be right in the middle, you know, that people have adequately addressed it and they've shown you this evidence. And, again, if you systematically look, you'll be able to pick where a particular guideline is in that. Q. At the bottom of the page is a section that says, "How to Rate." Do you see that? A. Uh-huh. Q. So, again, this is structure that I know

50 (Pages 194 - 197)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 52 of 58

CONFIDENTIAL

	Page 198		Page 200
1	Q. It's structured for somebody who's looking	1	Q. I acknowledge that it's eleven years old.
2	at guidelines to rate them; am I correct?	2	I acknowledge that you're an internal author,
3	A. Yes.	3	neither the lead nor the final.
4	Q. And here, to inform the rater's decision	4	Am I correct that the question that was
5	between, as you said, a spectrum from a weak 1 to a	5	being addressed, however, is how serious is the risk
6	strong 7, one of the items is "Reporting of the	6	of thromboembolic events for children who are
7	balance/trade-off between benefits and harms/side	7	hospitalized with inflammatory bowel disease?
8	effects/risks."	8	A. Yes.
9	Do you see that?	9	Q. And therefore, is it appropriate to take
10	A. Yes.	10	prophylactic measures to prevent thromboembolic
11	Q. So you would agree with me that a set of	11	events in the case of children?
12	guidelines that rates strongly on this aspect of	12	A. Yes.
13	rigour of development will in fact report in writing	13	Q. What is a thromboembolic event, if I'm
14	the balance or trade-off between benefits and risks	14	saying that correctly?
15	or harms that the drafters have considered?	15	A. You're saying it great. It's a stroke.
16	MS. LEVI: Object as to form.	16	Q. Is there anything else that falls within
17	A. So, I mean, again, this is a subjective	17	the category of a thromboembolic event?
18	reading that you're going to use on whether I think	18	A. Sure. Any blood clot. So it could be, you
19	a particular guideline has done this.	19	know most of them, unfortunately, are going to
20	And to be honest, in the context, it's not	20	predispose to stroke, but you worry about venous
21	just did they do it, but did they well write it, is	21	thromboemboli or, you know, DVT, deep venous
22	it clear and concise, is it you know, they're	22	thromboses, pulmonary emboli.
23	sort of telling you all these ways you can think	23	Q. All these, very serious medical
24	about what was written. Yes.	24	occurrences?
	Page 199		Page 201
1	Q. There's many ways it could be written.	1	A. Blood clots, yes.
2	My question for you was, do you agree,	2	Q. Okay. Just so I'm clear I know that
3	based on either this discussion of how to rate with	3	we're stating things am I correct that,
4	regard to Item 11 of the Rigour of Development, that	4	categorically, thromboembolic events are considered
5	a guideline that rates "strongly" on this particular	5	to pose a risk of serious harm?
6	point will be one which, perhaps among other things,	6	A. Yes.
7	actually reports how the authors evaluated the	7	Q. And, indeed, if we turn to Page 344, under
8	balance or trade-off between benefits and harms?	8	"Results" at the bottom, in the first column it
9	MS. LEVI: Object as to form.	9	states that "Of 532 patients" and correct me if
10	A. I would agree, if you are giving a	10	I'm wrong, these are all minors that were subject to
11	"strongly agree" rating of a guideline on this	11	this study, right?
12	Number 11, that you have it would be able to meet	12	A. Children, yes.
13	these particular rating guidelines.	13	Q. Of 532 patients who were admitted with
14	MR. BROOKS: Let me ask the reporter to	14	inflammatory bowel disease, almost 2 percent
15	mark as Exhibit 17 an article dated 2013, first	15	suffered thromboembolic events, correct?
16	author Zitomersky, with Dr. Lightdale as an internal	16	A. Yes.
17	author, entitled "Risk Factors, Morbidity, and	17	Q. And that's during their period of
18	Treatment of Thrombosis in Children and Young	18	hospitalization?
19	Adults."	19	A. These were all during the hospitalization,
		20	yeah.
20	(Document marked as Lightdale	120	•
	(Document marked as Lightdale Exhibit 17 for identification)	21	Q. Okay. And that's far above the rate you
20 21	Exhibit 17 for identification)	1	Q. Okay. And that's far above the rate you would expect among normal, healthy children,
20 21 22	Exhibit 17 for identification) Q. Dr. Lightdale, I'm going to guess that this	21 22	would expect among normal, healthy children,
20 21	Exhibit 17 for identification)	21	

51 (Pages 198 - 201)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 53 of 58

CONFIDENTIAL

1			
1	Page 202 Q. And in the second column of that same page,	1	Page 204
2	it says that four of the 10 had cerebrovascular	$\begin{vmatrix} 1\\2 \end{vmatrix}$	retrospective review and contributes to the literature of these type of retrospective reviews.
	-	$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	I think it can answer some questions. But
3	thrombosis, which is to say a stroke; am I correct? A. Correct.	4	it also it's limited because it's a retrospective
5	Q. One of which resulted in permanent	5	review at a single center.
6	cognitive defects, right?	6	Q. It raised enough concerns or questions
7	A. Yes.	7	that, based only on this small study, Boston
8	Q. And hemiparesis means partial paralysis?	8	Children's Hospital changed its practices with
9	A. Yes.	9	regard to children admitted with inflammatory bowel
10	Q. Okay. Very serious.	10	disease, correct?
11	One of those four patients required brain	11	A. Yeah. We made a decision to do that.
12	surgery? Is that what intracranial vascular surgery	12	Q. Dr. Lightdale, in weighing the risks and
	is?	13	benefits of a treatment for any condition in minors
14	A. I believe so.	14	that was not immediately life threatening, if the
15	THE WITNESS: Sorry, I will not	15	best available evidence indicated that that
16	MS. LEVI: You should make sure you answer	16	treatment increased the long-term risk of
17	his questions, and if you need to review it, take	17	thromboembolic events in neonatals by 20 percent,
18	the time to do that.	18	you would consider that to be an adverse effect that
19	THE WITNESS: Yeah.	19	needed to be given serious weight in the treatment
20	A. Well, in full disclosure, I don't	20	decision, would you not?
21	MS. LEVI: There's only one medical expert	21	MS. LEVI: Object as to form.
22	in this room, as far as I can tell.	22	A. Not necessarily. I'd need to know a lot
23	A. Yeah, so what I can tell you is we	23	more about what you're just explaining. I mean
24	described it as intracranial vascular surgery. So I	24	Q. I'm going to ask the reporter to read the
	Page 203		Page 205
1	don't know if it was catheterization.	1	question back and see if you have a more precise
2	I don't remember the patient. This was a	2	answer.
3	_		
1 3	long time ago.	3	
4	long time ago. Q. I understand, but catheterization or buzz	3 4	THE COURT REPORTER: "Dr. Lightdale, in
	Q. I understand, but catheterization or buzz		THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for
4		4	THE COURT REPORTER: "Dr. Lightdale, in
45	Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it	45	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately
45	Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not?	4 5 6	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available
4 5 6 7	Q. I understand, but catheterization or buzzsaw, either way it counts as brain surgery, does it not?A. Not necessarily, but I'm not a brain	4 5 6 7	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence"
4 5 6 7 8	Q. I understand, but catheterization or buzzsaw, either way it counts as brain surgery, does it not?A. Not necessarily, but I'm not a brainsurgeon.	4 5 6 7 8	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself.
4 5 6 7 8 9	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that 	4 5 6 7 8 9	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and
4 5 6 7 8 9 10	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. 	4 5 6 7 8 9 10	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of
4 5 6 7 8 9 10 11	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of 	4 5 6 7 8 9 10 11	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life
4 5 6 7 8 9 10 11 12	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a 	4 5 6 7 8 9 10 11 12	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would
4 5 6 7 8 9 10 11 12 13	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from 	4 5 6 7 8 9 10 11 12 13	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be
4 5 6 7 8 9 10 11 12 13 14	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from inflammatory bowel disease? 	4 5 6 7 8 9 10 11 12 13 14	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not?
4 5 6 7 8 9 10 11 12 13 14 15 16 17	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from inflammatory bowel disease? MS. LEVI: Object as to form. 	4 5 6 7 8 9 10 11 12 13 14 15 16 17	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not? MS. LEVI: Object as to form.
4 5 6 7 8 9 10 11 12 13 14 15 16	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from inflammatory bowel disease? MS. LEVI: Object as to form. A. Yeah, this is a single study retrospective 	4 5 6 7 8 9 10 11 12 13 14 15 16	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not? MS. LEVI: Object as to form. A. To me that's just too abstract. Like, I
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from inflammatory bowel disease? MS. LEVI: Object as to form. A. Yeah, this is a single study retrospective review of our population at our hospital. 	4 5 6 7 8 9 10 11 12 13 14 15 16 17	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not? MS. LEVI: Object as to form. A. To me that's just too abstract. Like, I need to understand what we're comparing it to and
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from inflammatory bowel disease? MS. LEVI: Object as to form. A. Yeah, this is a single study retrospective review of our population at our hospital. Q. And am I correct that that very small 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not? MS. LEVI: Object as to form. A. To me that's just too abstract. Like, I need to understand what we're comparing it to and what the non-treated group looks like, and also why
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from inflammatory bowel disease? MS. LEVI: Object as to form. A. Yeah, this is a single study retrospective review of our population at our hospital. Q. And am I correct that that very small sample size can raise questions and concerns, but it 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not? MS. LEVI: Object as to form. A. To me that's just too abstract. Like, I need to understand what we're comparing it to and what the non-treated group looks like, and also why are we treating.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from inflammatory bowel disease? MS. LEVI: Object as to form. A. Yeah, this is a single study retrospective review of our population at our hospital. Q. And am I correct that that very small sample size can raise questions and concerns, but it can't really answer questions? 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not? MS. LEVI: Object as to form. A. To me that's just too abstract. Like, I need to understand what we're comparing it to and what the non-treated group looks like, and also why are we treating. So I don't know that you can answer that
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. I understand, but catheterization or buzz saw, either way it counts as brain surgery, does it not? A. Not necessarily, but I'm not a brain surgeon. MS. LEVI: I object to the form of that question. Q. Now, am I correct that this sample size of patients who suffered thromboembolic events is small enough that this was not the type of study that could or did predict an incidence rate in a general in general among children suffering from inflammatory bowel disease? MS. LEVI: Object as to form. A. Yeah, this is a single study retrospective review of our population at our hospital. Q. And am I correct that that very small sample size can raise questions and concerns, but it 	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	THE COURT REPORTER: "Dr. Lightdale, in weighing the risks and benefits of a treatment for any condition in minors that was not immediately life threatening, does the best available evidence" MR. BROOKS: Let me re-ask it myself. Q. Dr. Lightdale, in weighing the risks and benefits of a treatment we'll stay abstract of a condition in minors that is not immediately life threatening, if it becomes known that that treatment increases the long-term risk of thromboembolic events in those children by 20 percent, you would consider that an adverse effect that needs to be given serious weight in the decision, would you not? MS. LEVI: Object as to form. A. To me that's just too abstract. Like, I need to understand what we're comparing it to and what the non-treated group looks like, and also why are we treating.

52 (Pages 202 - 205)

1	Page 206 Q. You cannot answer the question whether a 20	1	Page 208 term complications, like a lasting effect on memory
$\begin{vmatrix} 1\\2 \end{vmatrix}$	percent increase in risk of thromboembolic events or		is one of the complications I would want to be
$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	strokes is an adverse effect that you would need to	$\begin{vmatrix} 2\\ 3 \end{vmatrix}$	factoring in to my thinking about whatever we're
	at least give serious weight to?		• • •
4	• •	4	measuring.
5	MS. LEVI: I'm going to object as to form, and also it's a re-characterization of the question.	5	Q. And you're not willing to say, as you sit
6	You can answer it, if you can.	6	here today, Dr. Lightdale, that a long-term effect on that child's cognitive capabilities is a very
8	A. I mean, I think that when you do clinical		serious negative effect?
	studies, you're looking at complications. And so	8	MS. LEVI: Object as to form.
9	you want to understand what are the safety events,	10	A. It's still too abstract, the way we're
10		10	being asked this.
	and you're going to categorize them. And then you're going to take that into account as you look	11	Q. Do you have any familiarity or general
12			
13	at everything.	13 14	familiarity with the IQ scale? A. IQ?
14	It's just it's too I think to just go after throm I mean, I don't know that I can		-
15	after throm I mean, I don't know that I can answer the question more than that, is the bottom	15 16	Q. Yeah.A. Only, like, to talk about IQ.
16	line. I just would need a lot more context around	10	Q. Well, for instance, do you have a notion of
	it. So		- ·
18 19	Q. If a treatment resulted in 40 percent	18 19	the cognitive level of somebody who has an IQ measured at 80?
20	higher risk of thromboembolic events in the treated	20	A. That is you are profoundly not high IQ.
20	population, as compared to the untreated population,	20	Q. And do any of the conditions that you as
$\begin{vmatrix} 21\\22 \end{vmatrix}$	would you consider that an adverse effect that would	21	a professional treat and any of or any of the
22	need to be given serious weight in the cost/benefit	22	treatments that you as a professional are involved
23	analysis of a treatment for a condition that was not		in raise any risk of harm to a child's cognitive
27	-	27	
1	Page 207 immediately life threatening?	1	Page 209 capabilities?
2	MS. LEVI: Object as to form.	$\begin{vmatrix} 1\\2 \end{vmatrix}$	MS. LEVI: Object as to form.
3	A. I think all complications need to be	3	A. Not directly. So I mean, not that I
4	brought into the safety/benefit discussion of any	4	know of.
5	treatment.	5	I think that we worry about side effects.
6	Q. * If a treatment for a child that you were	6	I study sedation, so I worry about, you know, that's
7	considering if the best available evidence	7	going to potentially depress somebody's
8	suggested that that treatment would have a lasting		neurocognitive potential and have an effect. I
9	negative effect on the memory and learning		worry about sedation. I worry about sure, I'm
10	capability of that child, am I correct that you	10	worried about strokes in kids.
11	would consider that to be a very serious harm as you	11	Q. Right. If a treatment that you were
12	weighed the harms and benefits of treatments?	12	involved in or a clinical situation that you were
13	MS. LEVI: Object as to form.		involved in involved a risk of significant loss of
14	A. I would agree that you have to think about	14	cognitive capability to the child, am I correct that
15	all complications and that you want to be	15	you would consider that to be an important risk, for
16	transparent about them and understand them and weigh		instance, to disclose to parents?
17	them.	17	MS. LEVI: Object as to form.
18	Q. I didn't ask about all of them.	18	A. I think that would be an important risk I
19	MR. BROOKS: I ask the reporter to read back	19	would disclose to parents.
20	the question.	20	Q. And if a guideline you were developing
1	(* Question read)	21	involved a therapy which the best evidence suggested
21	(Question read)		
21 22		22	posed some risk of lasting cognitive impairment, you
	MS. LEVI: Preserving my objection for the record on rereading.	22 23	posed some risk of lasting cognitive impairment, you would expect to see that disclosed in the guideline,
22	MS. LEVI: Preserving my objection for the		posed some risk of lasting cognitive impairment, you would expect to see that disclosed in the guideline, would you not?

53 (Pages 206 - 209)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 55 of 58

CONFIDENTIAL

1	Page 210		Page 212
	MS. LEVI: Object as to form.	1	BY MR. BROOKS:
2	A. Not necessarily in the guideline if it's	2	Q. Dr. Lightdale, let me ask you to pick up
3	some risk. I need to understand just how much risk.	3	Exhibit 17 again, the "Risk Factors" document.
4	And then again, I believe in guidelines I trust	4	A. Yes.
5	and trustworthiness of guidelines. So I assume it	5	Q. And I want to clear up one thing. And,
6	would be covered.	6	again, I'm not trying to trick you with memory
7	Q. Do you know who Marci Bowers is?	7	tests.
8	A. (Shakes head)	8	You said more than once that this was about
9	That was "No." Sorry.	9	children, and if you turn to Page 345, there's a
10	MS. LEVI: You have to say it audibly.	10	list at the top of the 10 subjects who suffered
11	THE WITNESS: Yes. I apologize.	11	thromboembolic events, and all but one of them are
12	MS. LEVI: But if you need a break	12	older than 10, and some of them are in their younger
13	THE WITNESS: I was waiting to see if	13	20s.
14	anyone told me to say "No."	14	I just wanted to call your attention to
15	MS. LEVI: Do you	15	that and to clarify for the record that am I correct
16	THE WITNESS: I'm okay.	16	that the patients covered in this study were, for
17	MS. LEVI: Are you sure?	17	the most part, teens or very young adults?
18	THE WITNESS: Yes, I think so.	18	A. Yeah, this was yes. This was a
19	MS. LEVI: You should take a break when you	19	single-center study. And actually I saw somewhere
20	need it.	20	in it that we had the age range was 8 to 23, I
21	MR. BROOKS: We're going to be done	21	think.
22	shortly. Normally I offer breaks, but we're going	22	Q. Okay. And given that there were just 10
23	to be done shortly.	23	patients who had thromboembolic events this is
24	MS. LEVI: Okay.	24	going to be kind of a terminology question is
	Page 211		Page 213
1	BY MR. BROOKS:	1	this what one would describe as anecdotal evidence,
2	Q. Do you agree with me that if a treatment	2	or is it kind of rise to the level beyond that?
			of is it Kind of fise to the level beyond that?
3	recommended in a set of clinical guidelines involves	3	MS. LEVI: Object to the form.
3	recommended in a set of clinical guidelines involves a significant risk of permanent loss let me start		-
	-	3	MS. LEVI: Object to the form.
4	a significant risk of permanent loss let me start	3 4	MS. LEVI: Object to the form. A. This is not anecdotal. It's a
4 5	a significant risk of permanent loss let me start again.	3 4 5	MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our
4 5 6	a significant risk of permanent loss let me start again. Do you agree with me that if a treatment	3 4 5 6	MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital.
4 5 6 7	a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice	3 4 5 6 7	MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort?
4 5 6 7 8	a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child?	3 4 5 6 7 8	MS. LEVI: Object to the form.A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital.Q. Of a cohort?A. It's a cohort study.Q. Retrospective cohort study?A. Uh-huh.
4 5 6 7 8 9	a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a	3 4 5 6 7 8 9	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of
4 5 6 7 8 9 10	a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a	3 4 5 6 7 8 9 10	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for
4 5 6 7 8 9 10 11	a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it	3 4 5 6 7 8 9 10 11	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual
4 5 6 7 8 9 10 11 12 13 14	a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around	3 4 5 6 7 8 9 10 11 12 13 14	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant
4 5 6 7 8 9 10 11 12 13 14 15	a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies.	3 4 5 6 7 8 9 10 11 12 13 14 15	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that
4 5 6 7 8 9 10 11 12 13 14 15 16	 a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies. Q. And in that context, it's recognized as a 	3 4 5 6 7 8 9 10 11 12 13 14 15 16	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that
4 5 6 7 8 9 10 11 12 13 14 15 16 17	 a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies. Q. And in that context, it's recognized as a serious adverse effect; am I correct? 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that treatment would should and would disclose that
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies. Q. And in that context, it's recognized as a serious adverse effect; am I correct? A. Again, some I can think of treatments I 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that treatment would should and would disclose that risk as part of the discussion of risks and
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies. Q. And in that context, it's recognized as a serious adverse effect; am I correct? A. Again, some I can think of treatments I know of where this would be something you have to 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that treatment would should and would disclose that risk as part of the discussion of risks and benefits?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies. Q. And in that context, it's recognized as a serious adverse effect; am I correct? A. Again, some I can think of treatments I know of where this would be something you have to talk about with the families. So 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that treatment would should and would disclose that risk as part of the discussion of risks and benefits? MS. LEVI: Object as to form.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies. Q. And in that context, it's recognized as a serious adverse effect; am I correct? A. Again, some I can think of treatments I know of where this would be something you have to talk about with the families. So MS. LEVI: I need a break. 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that treatment would should and would disclose that risk as part of the discussion of risks and benefits? MS. LEVI: Object as to form. A. I'm just finding the questions too
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies. Q. And in that context, it's recognized as a serious adverse effect; am I correct? A. Again, some I can think of treatments I know of where this would be something you have to talk about with the families. So MS. LEVI: I need a break. MR. BROOKS: Fine. Pardon me. 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that treatment would should and would disclose that risk as part of the discussion of risks and benefits? MS. LEVI: Object as to form. A. I'm just finding the questions too abstract. There are so many things you need to look
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 a significant risk of permanent loss let me start again. Do you agree with me that if a treatment for a minor recommended in clinical practice guidelines raises a significant risk of permanent loss of sexual response, that that would be a serious harm to the affected child? MS. LEVI: Object as to form. A. So probably. You know, this is, like, a probably. This is long-term stuff. I think it probably comes up for oncologists around chemotherapies. Q. And in that context, it's recognized as a serious adverse effect; am I correct? A. Again, some I can think of treatments I know of where this would be something you have to talk about with the families. So MS. LEVI: I need a break. 	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 MS. LEVI: Object to the form. A. This is not anecdotal. It's a retrospective chart review of a cohort at our hospital. Q. Of a cohort? A. It's a cohort study. Q. Retrospective cohort study? A. Uh-huh. Q. If experience from a small number of patients suggests that a particular treatment for children poses a risk of lasting loss of sexual response and no large, statistically significant study has yet been done, would you expect that clinical practice guidelines addressing that treatment would should and would disclose that risk as part of the discussion of risks and benefits? MS. LEVI: Object as to form. A. I'm just finding the questions too

54 (Pages 210 - 213)

	Page 214		Page 216
1	know whatever. There's just a lot more details.	1	honestly you're asking the question in ways that I'm
2	Like, what were the other outcomes? What exactly	2	not sure what I'm answering. So I'd prefer not to
3	were we treating? It's almost hard to answer this	3	answer.
4	in the abstract. So	4	Q. What about
5	Q. If let me show you a document.	5	MS. LEVI: If you can't answer, you can say
6	MR. BROOKS: Let me ask the reporter to	6	you can't answer.
7	mark as Exhibit 18 an article from 1922 pardon	7	Q. What about my question is unclear to you?
8	me, 2022 entitled "The Dutch Protocol for Juvenile	8	A. Honestly, I'm not sure if you're I'm not
9	Transsexuals: Origins and Evidence," by Michael	9	sure if you're asking for me, like, my reaction,
10	Biggs.	10	or you know, there's a lot of ifs in there. So I
11	(Document marked as Lightdale	11	actually don't understand the data in order to be
12	Exhibit 18 for identification)	12	able to make any sort of, you know, useful
13	Q. Dr. Lightdale, can I say with some	13	statement.
14	confidence you haven't seen this one?	14	Q. Dr. Lightdale, you've offered opinions that
15	A. I definitely have not.	15	WPATH, in its preparation of their clinical practice
16	Q. And let me take you in this document to	16	guidelines, were, quote, exemplary, right?
17	Page I want to take you to Page 12. At the very	17	MS. LEVI: Answer a question if he's asked
18	bottom of Page 12 is a paragraph that begins, "Even	18	one.
19	less is known about the effects of puberty	19	MR. BROOKS: I have asked one.
20	suppression on sexual functioning." That's the	20	A. I gave an opinion that I thought the
21	topic sentence.	21	process that they describe on their website looks
22	And then you can turn over the page. Then	22	like what you would want a process to look like.
23	there's going to be a quote from Marci Bowers. Let	23	Q. Am I correct that you have not offered and
24	me make a representation to you who Marci Bowers is.	24	have not formed any opinion that WPATH's SOC-8 was
	Page 215		Page 217
1	Page 215 She is a past president of WPATH and is a surgeon	1	Page 217 in fact developed and written in compliance with any
1 2	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex,	1 2	
	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries		in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines?
2	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers,	2	in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form.
2 3 4 5	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties."	2 3	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines
2 3 4 5 6	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single	2 3 4 5 6	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I
2 3 4 5	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2,	2 3 4 5 6 7	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So
2 3 4 5 6 7 8	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really	2 3 4 5 6 7 8	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as
2 3 4 5 6 7 8 9	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero."	2 3 4 5 6 7 8 9	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was
2 3 4 5 6 7 8 9 10	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what	2 3 4 5 6 7 8 9 10	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a
2 3 4 5 6 7 8 9 10 11	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment.	2 3 4 5 6 7 8 9 10 11	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based
2 3 4 5 6 7 8 9 10 11 12	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case	2 3 4 5 6 7 8 9 10 11 12	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines?
2 3 4 5 6 7 8 9 10 11 12 13	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an	2 3 4 5 6 7 8 9 10 11 12 13	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form.
2 3 4 5 6 7 8 9 10 11 12 13 14	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases	2 3 4 5 6 7 8 9 10 11 12 13 14	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website
2 3 4 5 6 7 8 9 10 11 12 13 14 15	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm,	2 3 4 5 6 7 8 9 10 11 12 13 14 15	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methodology
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical practice guidelines addressing use of puberty	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit briefly, at the methods, looks, honestly, rigorous,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical practice guidelines addressing use of puberty blockers on minors would disclose that risk and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit briefly, at the methods, looks, honestly, rigorous, transparent and well thought out; that they put up a
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical practice guidelines addressing use of puberty blockers on minors would disclose that risk and discuss how it had been weighed by the team in their	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit briefly, at the methods, looks, honestly, rigorous, transparent and well thought out; that they put up a process that they were that they say that they
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical practice guidelines addressing use of puberty blockers on minors would disclose that risk and discuss how it had been weighed by the team in their cost/benefit analysis?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit briefly, at the methods, looks, honestly, rigorous, transparent and well thought out; that they put up a process that they were that they say that they followed. That's what I can form my opinion on.
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\end{array} $	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical practice guidelines addressing use of puberty blockers on minors would disclose that risk and discuss how it had been weighed by the team in their cost/benefit analysis? MS. LEVI: Object as to form.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit briefly, at the methods, looks, honestly, rigorous, transparent and well thought out; that they put up a process that they were that they say that they followed. That's what I can form my opinion on. Q. And the flip side of that is, you don't
$ \begin{array}{c} 2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\12\\13\\14\\15\\16\\17\\18\\19\\20\\21\\22\end{array} $	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical practice guidelines addressing use of puberty blockers on minors would disclose that risk and discuss how it had been weighed by the team in their cost/benefit analysis? MS. LEVI: Object as to form. A. This is just so outside my own scope of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit briefly, at the methods, looks, honestly, rigorous, transparent and well thought out; that they put up a process that they were that they say that they followed. That's what I can form my opinion on. Q. And the flip side of that is, you don't have the information you would need to form an
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	She is a past president of WPATH and is a surgeon who performs surgical procedures related to sex, gender-affirming surgeries or sex change surgeries on minors. And it indicates here, "Marci Bowers, who has performed over 2,000 vaginoplasties." And the quote here is, quote, "Every single child who was truly blocked at Tanner stage 2, has never experienced orgasm. I mean, it's really about zero." Now, that's not a study. That's, what shall we say, expert opinion, comment. My question for you is, if it's the case that children who are put on puberty blockers at an early stage of adolescent development in many cases fail to develop the ability to experience orgasm, would you consider that responsible clinical practice guidelines addressing use of puberty blockers on minors would disclose that risk and discuss how it had been weighed by the team in their cost/benefit analysis? MS. LEVI: Object as to form.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 in fact developed and written in compliance with any reliable or respected methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have no opinion on the guidelines themselves, because I didn't look at them, and I frankly wouldn't understand them. So Q. And you have not formed any opinion as to you have not formed any opinion that SOC-8 was in fact developed and written in compliance with a reliable methodology for developing evidence-based clinical practice guidelines? MS. LEVI: Object as to form. A. I have formed an opinion that the website and their discussion and description of the methods that they used, and today actually looking, albeit briefly, at the methods, looks, honestly, rigorous, transparent and well thought out; that they put up a process that they were that they say that they followed. That's what I can form my opinion on. Q. And the flip side of that is, you don't

55 (Pages 214 - 217)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 57 of 58

CONFIDENTIAL

	Page 218		Page 220
1	A. Correct. Yes.	1	SUGGESTED CORRECTIONS
2	MR. BROOKS: I have no further questions	2	RE: Brianna Boe, et al., etc., vs.
3	for the witness.		Hon. Steve Marshall, etc., et al.
4	MS. LEVI: Okay. The witness will read and	3	
5	sign.		WITNESS: Jenifer Lightdale, M.D., Vol. I
6	(Whereupon the deposition	4	
7	was concluded at 3:15 p.m.)	-	The above-named witness wishes to make the following
8	was concluded at 5.15 p.m.y	5	changes to the testimony as originally given: PAGE LINE SHOULD READ REASON
9		7	
10		8	
		9	
11		10	
12		11	
13		12	
14		13	
15		14	
16		15	
17		16	
18		17	
19		18	
20		19 20	
21		20	
22		22	
23		23	
24		24	
	Page 219		Page 221
1	Page 219 CERTIFICATE	1	Page 221 COMMONWEALTH OF MASSACHUSETTS)
1 2	CERTIFICATE		COMMONWEALTH OF MASSACHUSETTS)
2	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify	2	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.)
2 3	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my	23	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in
2 3 4	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and	2 3 4	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby
2 3 4 5	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript	2 3 4 5	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of
2 3 4 5 6	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and	2 3 4 5 6	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore
2 3 4 5 6 7	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony.	2 3 4 5 6 7	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the
2 3 4 5 6 7 8	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of,	2 3 4 5 6 7 8	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge
2 3 4 5 6 7 8 9	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony.	2 3 4 5 6 7 8 9	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy
2 3 4 5 6 7 8 9 10	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of,	2 3 4 5 6 7 8 9 10	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon
2 3 4 5 6 7 8 9 10 11	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of,	2 3 4 5 6 7 8 9 10 11	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting
2 3 4 5 6 7 8 9 10 11 12	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a
2 3 4 5 6 7 8 9 10 11 12 13	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of,	2 3 4 5 6 7 8 9 10 11 12 13	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness.
2 3 4 5 6 7 8 9 10 11 12 13 14	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or
2 3 4 5 6 7 8 9 10 11 12 13 14 15	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	C E R T I F I C A T E I, Jenifer Lightdale, M.D., do hereby certify that I have read the foregoing transcript of my testimony, and further certify, under the pains and penalties of perjury, that said transcript (with/without) suggested corrections is a true and accurate record of said testimony. Dated at, this day of, 2023.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	COMMONWEALTH OF MASSACHUSETTS) SUFFOLK, SS.) I, Carol H. Kusinitz, RPR and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 6th day of May, 2023, at 9:12 a.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of her knowledge touching and concerning the matters in controversy in this cause; that she was thereupon examined upon her oath, and her examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness. I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto

56 (Pages 218 - 221)

Case 2:22-cv-00184-LCB-CWB Document 564-26 Filed 05/28/24 Page 58 of 58

CONFIDENTIAL

	Page 222		Page 224
1	Under Federal Rule 30:		ERRATA for ASSIGNMENT #6671430
2	X Reading and Signing was requested	2	I, the undersigned, do hereby certify that I have read the transcript of my testimony, and that
3	Reading and Signing was waived	3	transcript of my testimony, and that
4	Reading and Signing was not requested.	4	There are no changes noted.
5		5	The following changes are noted:
6	In witness whereof, I have hereunto set my hand	6	
7	and affixed my notarial seal this 14th day of May,		Pursuant to Civil Procedure, Rule 30. ALA. CODE § 5-30(e)
8		7	(2017). Rule 30(e) states any changes in form or
9	0	Q	substance which you desire to make to your testimony shall be entered upon the deposition with a statement of the
10	Carol H. Kusinitz	0	reasons given for making them. To assist you in making any
11	0	9	such corrections, please use the form below. If additional
12	-		pages are necessary, please furnish same and attach.
12	-	10	
			Page Line Change
14			Descen for shores
15			Reason for change Page Change
16			
17			Reason for change
18			Page Line Change
19		18	
20			Reason for change
21			Page Line Change
22		21	Reason for change
23			Page Change
24		24	
	Page 223		Page 225
1	To: Jennifer Levi, Esq.	1	Page Line Change
	Re: Signature of Deponent CONF Jenifer Lightdale, M.D.		
3	Date Errata due back at our offices: 30 days	3	Reason for change
5	Greetings:	4	Page Line Change
6	This deposition has been requested for read and sign by	5	
7	the deponent. It is the deponent's responsibility to review the transcript, noting any changes or corrections		Reason for change
'	on the attached PDF Errata. The deponent may fill		Page Line Change
8	out the Errata electronically or print and fill out	8	
	manually.		Reason for change
9	Once the Errata is signed by the deponent and notarized,	10	Page Line Change
10	please mail it to the offices of Veritext (below).		Reason for change
11			Page Change
12	When the signed Errata is returned to us, we will seal	13	Enic Change
12	and forward to the taking attorney to file with the original transcript. We will also send copies of the		Reason for change
15	Errata to all ordering parties.	16	C
14		17	
15	If the signed Errata is not returned within the time	18	
16	above, the original transcript may be filed with the court without the signature of the deponent.		DEPONENT'S SIGNATURE
17	court minout the organizate of the deponent.	19	
18	Please Email the completed errata/witness cert page		Sworn to and subscribed before me this day of
10	to CS-SOUTHEAST@VERITEXT.COM	20	
	or mail to Veritext Production Facility		,
21	2000A Southbridge Parkway, Suite 400	21	
	Birmingham, AL 35209	22	NOTARY DURLIC (Mr. Commission Free)
	800-808-4958	23 24	NOTARY PUBLIC / My Commission Expires:
24		1 24	

57 (Pages 222 - 225)